(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 474 958 A2**

(12) # EUROPEAN PATENT APPLICATION

(21) Application number: **91104561.5**

(51) Int. Cl.5: **A61N 1/365**, A61B 8/06

(22) Date of filing: **22.03.91**

(30) Priority: **11.09.90 YU 1717/90**

(43) Date of publication of application:
18.03.92 Bulletin 92/12

(84) Designated Contracting States:
DE FR GB IT NL

(71) Applicant: **Ferek-Petric, Bozidar**
Sovinec 17
YU-41000 Zagreb(YU)
Applicant: **Breyer, Branco, Dr.**
Prilaz JA 79
YU-41000Zagreb(YU)

(72) Inventor: **Ferek-Petric, Bozidar**
Sovinec 17
YU-41000 Zagreb(YU)
Inventor: **Breyer, Branco, Dr.**
Prilaz JA 79
YU-41000Zagreb(YU)

(74) Representative: **Blumbach Weser Bergen**
Kramer Zwirner Hoffmann Patentanwälte
Radeckestrasse 43
W-8000 München 60(DE)

(54) **Cardiac electrotherapy system.**

(57) In a cardiac electrotherapy system comprising a blood flow velocity measurement cardiac pacing lead, means for ventricular pacing synchronous with atrial contractions and means fo a rate responsive pacing, pacing is controlled by means of processing of the diastolic filling waveform of blood flow through a cardiac valve.

EP 0 474 958 A2

This invention relates to cardiac electrotherapy, particularly to measurement of blood flow velocity characteristics within the heart and large blood vessels for the purpose of control of the electrotherapy.

Physiologic cardiac pacing is very important on temporary as well on permanent basis. Temporary pacing is usually applied either after cardiac surgery or during myocardial infarction because of the transient conduction disturbance or arrhythmia. Patients in rest have significantly improved cardiac output when ventricular contraction is synchronous with atrial filling of ventricles. This is very important for faster recovery after surgery or myocardial infarction. Furthermore, some arrhythmias like supraventricular tachycardias and extrasystolies may be prevented by means of physiologic pacing.

Patients with chronic conduction and rhythm disturbance have to receive a permanent implantable pacing system. They also have a significant contribution of atria to the hemodynamic benefit. There are two basic modes of physiologic cardiac pacing: sequential and synchronous. The sequential atrio-ventricular pacing is used to restore normal atrioventricular relationships. In this mode an atrium and a ventricle are paced by twin stimuli separated by an appropriate physiologic interval. However the heart rate is controlled by the pacemaker programme and does not vary according to the physiological needs. The synchronous cardiac pacing approximates most closely to the normal cardiac rhythm. The spontaneous atrial electrogram (P-wave) is sensed by an electrode usually in contact with the atrial endocardium and this is used to trigger the ventricle after an appropriate preset delay. Because the atrial rhythm is paced by our natural pacemaker sinus-atrial mode, the frequency varies naturally according to the body workload. Therefore the P-wave synchronous ventricular cardiac pacing is considered to be the most physiologic rate-responsive pacing.

There is a significant drawback of physiologic pacing systems which complicates the surgical procedure in comparison with non-physiologic pacing. The physiologic pacing requires the implantation of two leads: one atrial and one ventricular. Modern dual-chamber pacemaker have the ability to switch from sequential to synchronous pacing and vice versa according to the atrial rhythm which is monitored in the atrial channel. If the patient has a normal function of the sinus node and atria, the atrial lead is only used to sense the atrial activity and the ventricular lead is used to sense the ventricular activity and to pace the ventricles. Because the sensing of atrial activity may be done by an electrode floating within the right atrial cavity, a lot of effort has been done to design a single pass lead for P-wave synchronous ventricular pacing comprising the atrial and ventricular electrode on the same lead. Such a system has been described in the US-Patent No. 3,903,897. However, the atrial electrogram is having significantly lower amplitude when sensed by a floating electrode in comparison with an electrode having a direct contact with the atrial muscle. Therefore such systems have to comprise high sensitivity amplifier in the atrial channel. As a consequence, the high susceptibility on far fields appears, causing more likely occurrence of the various oversensing phenomena. Furthermore, many patients have low amplitude atrial electrogram and therefore the atrial undersensing is more frequent in such systems. The system described in the European Patent No. 311,019 monitors ventricular impedance continuously using electrode in ventricle without requiring additional sensing in the atrium. Detected impedance waveform can be used to trigger ventricular stimulus synchronously with atrial filling of ventricle. In this system the impedance changes because of the ventricular volume change caused by the atrial filling. In our system the flow velocity waveform through the tricuspid valve is measured which is the significant difference.

Very important technical and clinical performance of P-wave synchronous pacemakers is the upper rate behavior. Maximum pacing rate of ventricles is limited and therefore the atrial rhythm tracking by the ventricles will happen within the specified frequency range. The maximum tracking rate has to be programmable parameter in order to tailor the pacing frequency range according to the patients needs. Those who suffer from angina pectoris and impaired ventricular function are not capable to tolerate high tracking rates, while those with healthy cardiac muscle can tolerate high rate ventricular pacing. The synchronous pacing can be impaired by the atrial undulation and fibrillation when pacemaker sustains the maximum tracking rate during high atrial pathologic rhythm. Therefore even the intermittent atrial fibrillation is the contraindication for synchronous pacing. Patients suffering from intermittent atrial fibrillation would benefit a lot from a pacemaker comprising reliable atrial fibrillation detector and which could switch from synchronous to rate responsive pacing in the case of atrial fibrillation occurrence and vice versa, switch back to the synchronous mode upon the fibrillation termination. It would be very important that a pacemaker could monitor the ventricular performance and adapt the maximum tracking rate in such a way as to prevent angina and high-rate induced ischemia. It would be also important that a pacemaker could discriminate premature ventricular contractions with compensatory pause from those without the compensatory pause. Tachycardia is a condition in which the heart beats rapidly.

Pathologic tachycardia is the one which disturbs the hemodynamics causing the drop of systemic blood pressure. There are many types of pathologic tachycardias and the electrophysiology differentiates two major classes: supraventricular and ventricular tachycardias. Tachycardia is often the result of electrical feedback within the heart structures where the natural beat results in the feedback of an electrical stimulus which prematurely triggers another beat. There are several different cardiac pacing modes which may terminate the tachycardia. The underlying principle in all of them is that if a pacemaker stimulates the heart at least once shortly after a heartbeat, before the next naturally occurring heartbeat at the rapid rate, the interposed stimulated heartbeat disrupts the stability of the feedback loop thus reverting the tachycardia to sinus rhythm. Such a pacemaker was disclosed in the US-Patent No. 3,942,534 which, following detection of tachycardia, generates a stimulus after a delay interval.

The most hazardous arrhythmia is ventricular tachycardia which may progress in the lethal arrhythmia ventricular fibrillation. Because the ventricular tachycardia is not always successfully treated and terminated by antitachycardia pacing, the implantable cardioverter - defibrillator is used to deliver the high energy pulse shock in order to cause the cardioversion of ventricular tachycardia to sinus rhythm. Such an implantable device was disclosed in the US-Patent No. 4,614,192 comprising a bipolar electrode for R-wave sensing, the system utilizing heart rate averaging and probability density function for fibrillation detection. The similar system for cardioversion is disclosed in the US-Patent No. 4,768,512 which has the high frequency pulse delivery. All these systems deliver high energy shock through the special patch-electrodes such as described in the US-Patent No. 4,291,707. In order to simplify the surgical procedure, systems comprising superior vena cava electrode and subcutaneous electrode, such as described in the US-Patent No. 4,662,377, have been developed. The supraventricular tachycardia caused by atrial flutter or fibrillation can be also treated by implantable cardioverter such as described in the US-Patent No. 4,572,191.

The difficulty in the electrotherapy treatment of tachycardia is that the implantable apparatus has to comprise means for the accurate detection of pathologic tachycardia in order to deliver the electrotherapy pulses whenever the pathologic tachycardia occurs. The problem is that the heart rhythm increases its frequency physiologically whenever either the physical or the emotional stress occurs. The means for pathologic tachycardia detection must accurately differentiate the natural sinus tachycardia which may not be treated by means of electrotherapy from the pathologic tachycardia which has to be treated. Therefore the discrimination between normal and pathologic tachycardia on the basis of frequency measurement is not reliable. In order to overcome this problem numerous methods of tachycardia detection have been developed which are applicable in the implantable electrotherapy devices.

Such a system has been disclosed in the US-Patent No. 4,475,551 where the heart rate sensing as well as probability density function where used to distinguish between ventricular fibrillation and high rate tachycardia. More sophisticated system has been disclosed in the US-Patent No. 4,790,317 which can automatically recognize the pathologic rhythm by means of monitoring of the pulse sequence representing the ventricular electrical activity. At least two sensing positions i.e. to each ventricular epicardial surface are used, but more sensing points will obtain better discrimination between normal and pathologic rhythm.

The problems which may occur with such systems are susceptibility on electromagnetic interference and muscular noise, as well as improper gain of the heart beat detectors causing the undersensing of cardiac rhythm. Therefore some means for detecting of noise and for automatic sensitivity adjustment is desirable. Therefore the implanted pacemaker noise rejection system described in the US-Patent No. 4,779,617, as well as the automatic sensitivity control systems disclosed in the US-Patent No. 4,766,902 and US-Patent No. 4,768,511 have been developed.

The implantable cardioverting system usually comprises the cardiac pacing system because of the backup of bradycardial events which follow the cardioversion high voltage pulse. There are also patients who suffer from pathologic tachycardia as well as from bradycardia which has to be treated by cardiac pacing. Therefore the physiological sensor for control of the heart rate is desirable in order to obtain the rate responsive pacing. It is also possible that the cardioversion implantable device comprises a dual chamber physiologic pacing function. In such a system a sensor for atrial fibrillation detection would be important not only for the appropriate ventricular response on atrial rhythms, but also for differentiating supraventricular from ventricular tachycardia. There are many physiological control systems for rate responsive pacing, but only few of them can be used for tachycardia detection as well. As far as it is known to the inventors, none of these sensor systems can be used for ventricular tachycardia detection, rate responsive pacing, for atrial fibrillation detection, for pacing capture and for noise detection. The system disclosed in the US-Patent No. 4,774,950 comprises a circulatory systemic blood pressure mea-

surement system which detects the drop of pressure in the case of pathologic heart rhythm. A similar system is described in the US-Patent No. 4,791,931 where the pressure is measured by means of arterial wall stretch detection. Another system disclosed in the US-Patent No. 4,770,177 adjusts the pacing rate relative to changes in venous blood vessel diameter that is measured by means of piezoelectric sensor. The heart contractions change the ventricular chamber volume due to the inflow and outflow of blood thus varying the impedance within the chamber. The impedance measurement was used in the US-Patent No. 4,773,401 in order to obtain the physiological control of pacing rate. Furthermore the stroke volume and ventricular volume measurement is possible in the system described in the US-Patent No. 4,686,987 as well as in the US-Patent No. 4,535,774. The system disclosed in the US-Patent No. 4,802,481 comprises a transducer which detects the opening of the tricuspid valve in order to calculate the ejection time which is the sensor for rate responsive pacing. Obviously all these systems measure indirectly the mechanical contraction of the heart that is the consequence of the electrical depolarization and which has the performance influenced by sympathetic and parasympathetic nervous system as well as by circulatory catecholamines. The sympathetic stimulation and circulatory catecholamines increase the velocity of the contraction and therefore the hemodynamic forces are accordingly transferred to the circulatory system. In the case of pathologic rhythm having an electric depolarization disturbance, hemodynamics will be impeded. The quality of the mechanical cardiac contraction significantly differs in normal and pathologic rhythms. Not only the contraction but also the cardiac relaxation is influenced by circulatory catecholamines. In pathologic cardiac rhythm the relaxation of the heart will be critically impeded. As far as it is known to the inventors none of the systems uses the parameters of cardiac relaxation i.e. diastole for the cardiac electrotherapy control.

The aim of the present invention is to provide a cardiac electrotherapy system which will, in normal atrial rhythm, act in a synchronous mode and maintain atrio-ventricular synchronism, yet with the need for implantation of a single lead.

It is an object of the present invention to provide a pacemaker comprising sensors for rate responsive ventricular pacing.

It is a further object of the present invention to provide a pacemaker comprising a reliable means for atrial fibrillation detection and which will maintain the rate responsive pacing while the atrial fibrillation is sustained.

It is another object of the present invention to provide a cardiac pacemaker which will monitor the right ventricular filling dynamics in order to estimate the ventricular muscle performance, and which will automatically reprogram the maximum tracking rate in such a way as to prevent the angina pectoris and high-rate induced myocardial ischemia.

It is a special object of the present invention to provide a pacemaker capable to detect premature ventricular contractions without as well as with compensatory pause.

It is another special object of this invention to provide a pacemaker capable to confirm the ventricular capture.

It is also a special object of this invention to provide a pacemaker capable to discriminate the sinus tachycardia from the pathologic tachycardia.

It is a further object of the present invention to provide an ultrasonic Doppler synchronized cardiac electrotherapy device which positively controls the direction of Doppler measurement with high accuracy and reliability. Any arbitrary movements of the transducer means within the blood vessel or a chamber of the heart shall be restricted and any floating of the pacing electrode shall be avoidable.

In carrying out the invention, the blood flow along a blood vessel or within the heart is monitored with a device for the blood flow velocity measurement mounted on a cardiac pacing lead.

The flow waveform through the tricuspid valve is used for synchronization and control of ventricular cardiac pacing.

The invention is characterized by the features of claim 1. Means for an atrial fibrillation detection and means for the ventricular tachycardia and fibrillation detection are preferable provided. Further aspects of the invention are described in the remaining claims.

The invention will be more readily understood by reference to the following description and accompanying drawing in which

Fig. 1 is a cross-sectional four chamber view of the human heart showing approximately the anatomic structures and a cardiac pacing lead comprising a device for blood flow velocity measurement implanted in the right heart.

Fig. 2 is an illustration of a typical waveform of the blood flow velocity measurement through the tricuspid valve, relative to the electrocardiogram in normal atrial function.

Fig. 3 is an illustration of a typical waveform of the blood flow velocity measurement through the tricuspid valve, relative to the electrocardiogram in atrial fibrillation.

Fig. 4 is an illustration of the measurements of the flow velocity waveform to obtain the rate responsive pacing sensors.

Fig. 5 is a perspective view of an unipolar cardiac pacing lead comprising axially polarized piezoelectric transducer for pulsed wave flow measurement, showing the distal part of the lead,

Fig. 6 is a perspective view of an unipolar cardiac pacing lead comprising a pair of axially polarized transducers for continuous wave flow measurement, showing the distal part of the lead,

Fig. 7 is a detailed axial cross-sectional view of the segment of pacing leads from Fig. 1 and 2 disclosing the part of lead where the flow measurement transducer is fixed,

Fig. 8 is an axial cross-sectional view of the distal part of pacing lead from Fig. 2,

Fig. 9 is an axial cross-sectional view of the segment of unipolar cardiac pacing lead comprising radially polarized transducers for continuous wave flow measurement,

Fig. 10 is a view along the distal part of the lead such as shown in Fig. 5 disclosing the principle of ultrasonic radiation,

Fig. 11 is a cross-sectional four chamber view of the human heart showing approximately the anatomic structure and a cardiac pacing lead from Fig. 5 and 7 implanted in the right heart,

Fig. 12 is an illustration of a typical waveform of the pulsed Doppler blood flow measurement through the tricuspid valve, relative to the electrocardiogram,

Fig. 13 is a simplified block diagram of a pacemaker comprising the pulse Doppler flow measurement circuit,

Fig. 14 is a flow-chart illustrating the logical function of a pacemaker from Fig. 13,

Fig. 15 is a detailed axial cross-sectional view of the segment of another pacing lead, disclosing the part of lead where a transducer made from a piezo film is fixed,

Fig. 16 is a detailed axial cross-sectional view of the segment of a further pacing lead, wherein pairs of plate-like transducers for velocity measurement are mounted at the circumference of the lead,

Fig. 17 is the transversal cross-section F-F as indicated in Fig. 16,

Fig. 18 is a side-view of the lead of Fig. 16 and 17 and

Fig. 19 illustrates the situation of Fig. 18 rotated by an angle of 90°.

In the embodiment of Fig. 1 the pulsed wave flow measurement pacing lead is shown within the anatomic structures of the human heart. The heart is disclosed in the four chamber cross-section and the myocardial cross-section is visible of the left-ventricular wall 10, the right-ventricular wall 11, the interventricular septum 12, the left-atrial wall 13 and the right atrial wall 14. Two chambers of the left heart, left ventricle 15 and left atrium 16 are separated by the mitral valve 17. The left ventricular outflow tract consists of the aortic valve 18 and aorta 19. A cardiac pacing lead 20 is implanted through the vena cava superior 21 and the right atrium 22 in the right ventricle 23, with its pacing electrode 24 located in the apex of the right ventricle. In the low right-atrial region, in the proximity of the tricuspid valve 25, the lead 20 comprises a flow velocity measurement assembly 26. Because the lead is bent in rhythm of cardiac contractions, it is important that the flow velocity measurement device is designed in such a way as to prevent the distortion of the tricuspid flow waveform pattern caused by movements of the lead itself. There are several methods of flow velocity measurement. The ultrasonic methods either Doppler or phase shift, are very accurate and longterm stable but because of high current drain, these are intended to be used in external devices. The flow measurement device may be also a pressure gradient type sensor. It may be also the device which measures the capacitance change in the vicinity of the tricuspid valve. Very accurate is the electromagnetic type flowmeter. The thermal transport flow transducers may also be used. However, despite of the method used, the pacing control principle remains the same as it is shown in the following Figures.

In the embodiment of Fig. 2 an example of the electrocardiogram and corresponding tricuspid flow waveform is disclosed. P waves, QRS complexes and T waves are designated illustrating a normal ECG. The flow velocity waveform through the tricuspid valve is disclosed under the ECG in time correlation to the ECG. Important timing intervals are designated like measurement refractory period (MRP), flow velocity measurement interval (FMI) and atrio-ventricular interval. Every sensed or paced ventricular event initiates the flow velocity measurement refractory period which is followed by the flow velocity measurement interval. These intervals are inversely proportional to the heart frequency. After the repolarization of the heart which caused

the T wave 30, the relaxation of the heart muscle causes the early diastolic filling wave 31 having the peak blood velocity E. The following atrial depolarization causes the P wave 32 and corresponding atrial muscle contraction which pumps additional blood quantity producing the blood flow wave 33 having peak velocity A. The ratio of peak velocities E.A is a hemodynamic parameter showing the cardiac muscle performance. The similar waveform is obtained when measuring the mitral valve flow where peak velocities are having greater values (in order of 1 m/s) in comparison with tricuspid valve velocities being half slower. Another hemodynamic parameter being used in clinical practice is the ratio of the time integrated wave E and the time integrated wave A. The example is given for the healthy human heart, but pathologic conditions may disturb this relations. This is used in this invention for diagnostic purposes. First of all, synchronized pacing is obtained in this invention by means of sensing the flow velocity A wave and synchronizing the ventricular pacing with it, and not with the endocardial P wave as it is done in conventional VDD pacing systems. This is illustrated in the last complex of disclosed ECG strip where the subsequent A-wave 34 is sensed and the atrioventricular interval 35 is initiated (shown as a black bar). At the end of the A-V interval the pacing impulse 36 is generated producing the paced R-wave 37. It is obvious that A-V intervals in this system are much shorter than in systems which sense the atrial electrogram. In the case of severe ventricular arrhythmia like ventricular fibrillation, E waves disappear because the missing ventricular contraction causes missing ventricular relaxation. Ventricular tachycardia will produce irregular peak velocity of E waves having significantly lower magnitude of that in normal ventricular contraction. Decrease of peak velocity magnitude is dependent of the tachycardia frequency. This is used for reliable life threatening arrhythmias detection. Any ischemic episode like pacing induced high rate ischemia will change the ratio of peak velocities as well as the ratio of time integrals. This is used for physiologic maximum tracking rate response to prevent angina pectoris. The E/A ratio is significantly decreased in the case of ventricular premature contraction without the compensatory pause, which enables the exact detection and counting of the premature ventricular contractions.

In the embodiment of Fig. 3 an example of the electrocardiogram and corresponding tricuspid flow waveform is disclosed. QRS complexes and T waves are designated illustrating the atrial fibrillation rhythm. The flow velocity waveform through the tricuspid valve is disclosed under the ECG in time correlation to the ECG waveform. The QRS complex is proceeded by a T-wave 38 which represents the cardiac repolarization. The consequence of the cardiac muscle relaxation is an early diastolic filling wave 39 having peak velocity E. Because of the atrial fibrillation there is no atrial filling wave as in previous Fig. This example shows how easy and reliable detection of atrial fibrillation may be done which is actually the detection of disappearance of the atrial filling wave.

In the embodiment of Fig. 4, there is disclosed the ECG strip with corresponding tricuspid flow velocity waveform in atrial fibrillation rhythm when the rate responsive pacing is necessary. This Fig. is an example of measurements which have to be done on both waveforms, ECG and tricuspid flow waveform, in order to obtain the sensors for rate responsive pacing. Circulatory catecholamines directly influence the interval between the QRS complex and the corresponding following E wave as well as they influence the rate of diastolic filling. Therefore the sensors for rate responsive pacing are available in this system. The QRS complex 40 is followed by a T-wave 41. As a consequence of the cardiac muscle repolarization the relaxation occurs causing the E-wave 42 in tricuspid flow waveform. The pacemaker spike 43 produces the stimulated QRS complex 44 and consequently the proceeding T-wave 45 causes the another E-wave 46. The peak velocity E_p of the rapid filling is continuously measured for every heart beat. The rapid filling period (RFP) which is the E-wave duration is measured as well as the first derivative of the E-wave onset which is the diastolic filling acceleration (DFA). Also the interval QE between the pacemaker spike and the E-wave peak is measured. In the case of exercise the circulatory catecholamines concentration increases and the peak velocity E_p of diastolic filling increases as well as the diastolic filling acceleration, while the QE interval and the rapid filling period will be shortened. The adequate algorhythms within the microprocessor of the implanted device will process the above mentioned measured data in such a way as to physiologically increase the cardiac pacing rate in the case of physical exercise of a patient.

In the embodiment of Fig. 5 a pulsed wave flow measurement cardiac pacing lead consists of a plastic body 410 having a pacing electrode 411 on the tip. A pulsed wave flow measurement piezoelectric transducer 412 of cylindric form is built into the lead and fixed at its surface at a distance from the tip electrode. The distance is such that, in normal operation, the transducer 412 is positioned near to and proximal to the tricuspid heart valve. There is a plastic ultrasound lens 413 distally by the transducer which determines the direction of ultrasound transmission and reception. A reflective or absorptive backing 414 is fixed proximally by the transducer. The transducer is of a cylindrical

form poled lengthwise and with electrodes on its top an bottom. In this way the ultrasound directivity characteristics are directed along the catheter. This particular property makes it virtually insensitive to flows in other directions than the axial. At the proximal end of the lead, which is not shown, there is a connector system for the connection of the lead to the electronic circuits.

In the embodiment of Fig. 6 a continuous wave flow measurement cardiac pacing lead consists of a plastic body 420 having a pacing electrode 421 on the tip. There are two piezoelectric transducers 422 and 423 mounted coaxially with the lead at a distance from the tip. The distance is such as to position the transducers 422 and 423 in the vicinity of the tricuspid heart valve. The transducers 422 and 423 are of a ring or cylindric form, with electrodes at their top and bottom (not shown) connected via built in lead conductors (not shown) to the lead connector (not shown) at the proximal end of the lead which is not shown. The plastic ultrasound lenses 424 and 425, as well as the absorptive or reflective backings 426 and 427 control the direction of ultrasound transmission and reception, respectively.

In the embodiment of Fig. 7 there is disclosed a detailed axial cross-section of the lead and the flow measurement transducer either from the lead of Fig. 5 or from the distal transducer of the lead according to Fig. 6. Within the plastic body 430 there is a lead conductor 431 having a stylet channel 432 which connects the pacing electrode at the distal end (not shown) with the connector at the proximal end (not shown) of the lead. The cylindrical piezoelectric transducer 433, mounted coaxially on the plastic body 430, has two electrodes 434 and 435 which are co-fired at the proximal and distal end of the transducer in such a way as to pole the transducer axially. The transducer electrode 434 is electrically connected with the pacing lead conductor 431 by means of the connection bridge 436. The transducer electrode 435 is electrically connected with another lead conductor 437 by means of another connection bridge 438. An ultrasonic lens 439 is fitted and glued by the transducer. The lens 439 is of the form of a tapered ring and represents an essentially conical ultrasonic lens. At the end opposite to the lens of the transducer there is a backing 440 glued onto the electrode 435. The backing 440 is built of either an air equivalent material such as expanded plastic or of an ultrasound absorbing material such as synthetic resin filled with metal powder. This backing is of such a tapered form that it does not obstruct the indwelling procedure. The lens 439, the transducer 433 and the backing 440 are covered with a thin sheath 441 of electrically insulating material not thicker than 5% of the ultrasound wavelength used.

The disclosed lead assembly comprises helically wounded coaxial lead conductors with a stylet channel which is the technology used in leads for permanent implantation. Simpler design is possible for temporary cardiac leads using ordinary insulated copper wires in a plastic tube. The plastic body may consist of multiple insulation sheaths i.e. plastic tubes between and over the lead conductors.

In the embodiment of Fig. 8 the distal part of the continuous wave flow measurement pacing lead consists of a plastic body 50 having an electrode 51 on its tip which is electrically connected to the inner lead conductor 52 by means of either conductive gluing or soldering member 53. The inner lead conductor 52 has a stylet channel 54 and on the proximal part of the lead (not shown) it is terminated with connector pin (not shown) on the connector assembly (not shown). Proximally from the tip there is a flow measurement assembly comprising two cylindric piezoelectric transducers 55 and 56 which are mounted coaxially with the plastic body 50. Transducer 55 comprises co-fired electrodes 57 and 58 which pole the transducer 55 axially. The electrode 57 is electrically connected to the inner lead conductor 52 by means of conductive bridge 59. In the same manner, the electrode 58 is connected to the middle coaxial lead conductor 60 by means of the conductive bridge 61. In disclosed example, transducer 55 is electrically connected to the electronic circuits (not shown) through lead conductors 52 and 60 by means of said connector assembly (not shown) at the proximal end of the lead (not shown). Transducer 56 comprises co-fired electrodes 62 and 63 which pole the transducer 56 also axially. The electrode 62 is electrically connected to the middle lead conductor 60 by means of the conductive bridge 64. In the same manner, the electrode 63 is connected to the outer lead conductor 65 by means of the conductive bridge 66. In disclosed example, transducer 56 is electrically connected to the electronic circuits (not shown) through lead conductors 60 and 65 by means of the said connector assembly (not shown) at the proximal end of the lead (not shown). Ultrasonic lenses 67 and 68 are fitted to the transducer electrodes 57 and 62, respectively, and glued. The lenses 67 and 68 are of the form of tapered rings and represent essentially conical ultrasonic lenses. At the opposite end of the transducers 55 and 56, backings 69 and 70 are fitted to the transducer electrodes 58 and 63, and glued. The backings are made of either an air equivalent material such as expanded plastic or of an ultrasound absorbing material such as synthetic resin filled with metal powder. Backings are of such a tapered form that they do not obstruct the indwelling procedure. The distance between trans-

ducers 55 and 56 is much larger than the ultrasound wavelength within the body tissues. The distance of the transducers 55 and 56 from the lead tip and electrode 51 is such as to enable the continuous wave flow measurement through the tricuspid valve while the electrode 51 is positioned in the apex of the right ventricle. Transducers 55 and 56, lenses 67 and 68, as well as backings 69 and 70 are covered with electrically insulating plastic sheets 71 and 72 respectively, which are not thicker than 5% of the ultrasound wavelength used. Disclosed lead assembly comprises helically wounded coaxial lead conductors and a stylet channel which a typical design for permanent leads. Simpler design is possible using standard insulated copper wires in a plastic tube which is typical design for disposable temporary pacing leads.

In the embodiment of Fig. 9 there is disclosed a flow measurement assembly of the continuous wave flow measurement pacing lead. The lead comprises a plastic body 80 and piezoelectric transducers 81 and 82 which are embedded within the body 80. Transducer 81 is poled radially by means of electrodes 83 and 84, while the transducer 82 is poled radially by means of electrodes 85 and 86. Transducers 81 and 82 can be made in cylindrical form, or can be made as a folded piezoelectric plastic foil (PVDF type). The inner lead conductor 87 having a stylet channel 88 is terminated on its distal end with a pacing electrode (not shown) and on its proximal end with a connector pin (not shown) as part of connector assembly (not shown). Conductor 87 is electrically connected with electrode 83 by means of a conductive bridge 89. The middle coaxial lead conductor 90 is electrically connected to the electrode 84 by means of conductive bridge 91 as well as to the electrode 86 by means of a conductive bridge 92. The outer coaxial lead conductor 93 is electrically connected to the electrode 85 by means of a conductive bridge 94. In such a way of electrical connections transducer 81 is connected to the external electronic circuits (not shown) through coaxial lead conductors 87 and 90 by means of said connector assembly (not shown) at the proximal end (not shown) of the lead. In the same manner the transducer 82 is connected to the said external electronic circuits through coaxial lead conductors 90 and 93 by means of said connector assembly. The beam tilt needed for appropriate blood velocity measurement is achieved by using ultrasound lenses 95 and 96, as well as by means of reflective coatings 97 and 98.

In the embodiment of Fig. 10 there is a side view of the distal part of the continuous wave flow measurement pacing lead similar to that from Fig. 9 illustrating the ultrasonic beam tilt. The lead comprises a plastic body 100 having a pacing electrode 101 on the tip. The ultrasonic lenses 102 and 103 as well as reflective coatings 104 and 105 direct the sensitivity of transducers in such a way as it is illustrated by means of dashed lines which designate the geometric shape of the axial cross-section of the ultrasonic beams. The ultrasound beams of both transducers are axially symmetric having geometric shapes of a top-cut hollow cone, in such a way as to avoid the intersection of ultrasonic beams with the lead itself. The geometric inter-section of these two beams is a sensitivity volume axially symmetric with the axis of the lead, its axial cross-section 106 being two rhomboids. The blood velocity is measured within the sensitivity volume. Disclosed physical principle of the ultrasonic beams tilt and sensitivity volume as a beam intersection may be generalized for all continuous wave flow measurement leads, also for the lead from Fig. 6 and 8. The same geometrical shape of the ultrasonic beam is achieved by means of transducer assembly from Fig. 7 and lead from Fig. 5 for use with PW Doppler systems. Furthermore, it is very important for CW as well as for PW Doppler lead that the ultrasonic beam is hollow in such a way as to prevent the intersection of beam with the lead itself.

In Fig. 11 the pulsed wave flow measurement pacing lead is shown within the anatomic structures of the human heart. The heart is disclosed in the four chamber cross-section and the myocardial cross-section is visible of the left-ventricular wall 110, the right-ventricular wall 111, the interventricular septum 112, the left-atrial wall 113 and the right-atrial wall 114. Two chambers of the left heart, left ventricle 115 and left atrium 116 are separated by the mitral valve 117. The left ventricular outflow tract consists of the aortic valve 118 and aorta 119. A cardiac pacing lead 120, such as disclosed in Fig. 5, is implanted through the vena cava superior 121 and the right atrium 122 in the right ventricle 123, with its pacing electrode 124 located in the apex of the right ventricle. In the low right-atrial region above the tricuspid valve 125, the lead 120 comprises a flow measurement assembly 126 such as disclosed in Fig. 7. Dashed lines emanating from the flow measurement assembly 126 designate the cross-section of the axially symmetric ultrasonic beam. The ultrasonic beam is directed in such a way as to enable the pulsed wave measurement of the blood flow through the tricuspid valve 125. Because the lead is bent in rhythm of cardiac contractions, it is important that the ultrasonic beam does not intersect the lead which could provoke the distortion in the tricuspid flow pattern caused by movements of the lead.

In the embodiment of Fig. 12 and example of the electrocardiogram and corresponding pulsed

wave Doppler waveform is disclosed. P waves, QRS complexes and T waves are designated illustrating a normal ECG. The envelope of the pulsed wave Doppler waveform through the tricuspid valve is disclosed under the ECG in exact time correlation to the ECG. Important timing intervals are designated like Doppler refractory period DRP, Doppler measurement interval DMI and atrio-ventricular interval. After the repolarization of the heart which caused the T wave 150, the relaxation of the heart muscle causes the early diastolic filling wave 151 having the peak blood velocity E. The following atrial depolarization causes the P wave 152 and corresponding atrial muscle contraction which pumps additional blood quantity producing the blood flow wave 153 having peak velocity A. The ratio of peak velocities E/A is a hemodynamic parameter showing the cardiac muscle performance. The same Doppler waveform is obtained when measuring the mitral valve flow where peak velocities are having greater values (in order of 1 m/s) in comparison with tricuspid valve velocities being half slower. Another hemodynamic parameter being used in clinical practice is the ratio of the time integrated wave E and the time integrated wave A. The example is given for the healthy human heart, but pathologic conditions may disturb this relations. This is used in this invention for diagnostic purposes. First of all, synchronized pacing is obtained in this invention by means of sensing the Doppler A wave and synchronizing the ventricular pacing with it, and not with the endocardial P wave as it is done in conventional VDD pacing systems. This is illustrated in last complex where following A-wave 154 is sensed and the atrio-ventricular interval 155 is initiated (shown as a black bar). At the end of the A-V interval the pacing impulse I is generated producing the paced R-wave 156. It is obvious that A-V intervals in this system are much shorter than in systems which sense the atrial electrogram. In the case of atrial fibrillation Doppler A waves disappear and this is used for atrial fibrillation detection. In the case of severe ventricular arrhythmia like ventricular tachycardia and fibrillation, E waves disappear because the missing ventricular contraction cause missing ventricular relaxation. This is used for reliable life threatening arrhythmias detection. Any ischemic episode like pacing induced high rate ischemia will change the ratio of peak velocities as well as the ratio of time integrals. This is used for physiologic maximum tracking rate response to prevent angina pectoris. The E/A ratio is significantly decreased in the case of ventricular premature contraction without the compensatory pause. Circulatory catecholamines directly influence the interval between the QRS complex and the corresponding following Doppler E wave as well as they influence the rate of diastolic filling. Therefore the sensors (data) for rate responsive pacing are available in this system.

In the embodiment of Fig. 13 a generalized block diagram of a microprocessor controlled unipolar pacemaker is disclosed. Microprocessor 160 comprises a memory 161 where various data are kept in registers and counters generated by the software. Crystal oscillator 162 is producing exact time base and reed switch 163 may produce various functions known in the art. The implantable unit must be programmable by means of an external programmer and various telemetric functions are desirable. These functions are obtained by the programming and telemetry circuit 164 and radio-frequency communications circuit 165 with antenna. The output pacing circuit 166 comprises a programmable pulse generator, voltage double and protection circuit as it is known in the art. The programmable gain bandpass filter-amplifier 167 senses the endocardial ventricular signal picked-up by the electrode during spontaneous ventricular heart beat. Doppler circuit 168 detects and measures the blood flow and the analog to digital converter circuit 169 prepares the envelope of Doppler waveform for digital processing. Positive pole of pulse generator in circuit 166 and one pole of sensing amplifier 167 is connected to the pacemaker can 170. Negative pole of the pulse generator in circuit 166 and another pole of the sensing amplifier 167 is connected to the pin 171 of a bipolar connector assembly. Pin 171 is electrically connected to the active pacing electrode in the ventricle and to the ultrasonic transducer when the lead such as disclosed in Fig. 5 and 7 is coupled to the connector assembly. Another terminal of Doppler circuit 168 is connected to the pin 172 of a bipolar connector assembly being connected to the ultrasonic transducer of the lead such as described in Fig. 5 and 7. Disclosed system may have unipolar pacing and sensing function through the pacemaker can 170 and connector pin 171, as well as Doppler measurements through the connector pins 171 and 172. The Doppler circuit may be designated to operate in the PW mode or in the CW mode. For the PW mode one can use lower frequencies (down to 2 MHz) with the range gate set to near distance (up to 1.5 cm). In the CW mode the system operates at frequencies above 5 MHz, preferably at more than 8 MHz reducing the effective range to the necessary value. The data are measured at characteristic phases of cardiac cycle, i.e. in diastole, thereby saving energy from the pacemaker power source. The data collected in this way are fed into the pacemaker microprocessor and the data are then used for controlling the pacemaker. The Doppler electronic circuit can measure blood flow velocity using Doppler effect

and to process the data to yield pulsatility and flow figures for pacemaker control. It can also measure the peak velocity as well as the time integral of the Doppler flow waveform envelope. Disclosed system comprises the connector assembly which is intended for use with pulsed wave Doppler lead for unipolar pacing. More complicated connector must be used in continuous wave system as well as in bipolar pacing system. Disclosed system can be incorporated in the implantable defibrillator-cardioverter as a pacing back-up system as well as a reliable system for fibrillation detection.

In the embodiment of Fig. 14, a generalized flow-chart discloses one of many possible modes how the microprocessor polls various circuits in order to logically connect the function of Doppler blood flow measurement and cardiac pacing. Other possible functions of a microprocessor such as tachycardia detection algorhythm, electromagnetic interference response, programming, telemetry interrogation and many other basic functions are not shown because these are well known in the art and are not the subject of this application. Sensing 200 of the spontaneous R-wave starts the routine and stops 201 the Doppler measurement interval DMI which is the time while the Doppler circuit is enabled for detection and measurement. Logical diagram connector is designated by 202 leading to the triggering 203 of the pacing impulse. In this example the rate responsive sensor is the QE interval which is the time interval from either the paced or sensed QRS complex to the corresponding Doppler E wave. Therefore the measurement of this interval is started 204 by resetting the counter "RR". The Doppler circuit is enabled after a certain delay from the QRS complex, which is called Doppler refractory period DRP. The DRP duration depends on the heart rate and becomes shorter as the heart rate increase and vice versa. Therefore the heart rate is read 205 from the memory register "HR" and the DRP is calculated 206 according to the predetermined relation. This calculation may be in units of the "RR" counter and upon the DRP termination 209 the DMI is started 208. Microprocessor waits 209 for the occurrence of the E wave as long as is the programmed escape interval 210. Logical diagram connectors are designated by 211, 212 and 213. Any first Doppler wave will be assigned as an E wave and upon the occurrence 211 several actions will be initiated 213. The counter "RR" is stopped 214, now containing the QE interval duration. The counter "EE" is also stopped 215, now containing the interval between the former and the latter E wave, which is the numerical inverse of the actual heart rate. Doppler circuit measures 216 the peak blood flow velocity and stores its value in the memory register "E". The word in counter "EE" is read 217 and stored in a "First In Last Out" (FILO) type memory register, and the counter "EE" is reset 218 starting to measure the next E to E wave interval. The DRP is calculated 206 according to the average heart rate during the last several heart beats. Therefore the content of FILO memory register is averaged 219 and the result is stored in the memory register "HR". The capacity of FILO i.e. the number of FILO register words is equal to the number of last beat to beat intervals which are averaged for the average heart rate i.e. the content of register "HR". Microprocessor checks if the heart beat is with or without compensatory pause thus enabling to classify the premature ventricular contractions (PVCs) without the compensatory pause. This kind of PVCs produce significantly lower peak velocity of the early ventricular filling in comparison with the normal beat and PVCs with compensatory pause. Therefore the preprogrammed critical peak velocity Ec is read 220 from the memory and compared 221 with the measured peak velocity stored in register "E". If there was a decrease of the rate of early diastolic filling, the beat is considered to be a PVC without compensatory pause and the memory register "PVC" is incremented 222. The "PVC" memory register keeps the number of PVCs for later interrogation by the programmer for the diagnostic purpose. The software routine may now enter the waiting loop for the second Doppler wave 223 which may last till the end of the programmed escape interval 224. The second wave is considered to be the atrial filling A-wave. If the A-wave occurs, the software will continue to the synchronized pacing routine 225. If the A-wave is missing, the microprocessor considers that the atrial fibrillation occurred and the rate responsive pacing routine will proceed 226.

Logical diagram connectors are designated by 225, 226, 227 and 239.

The routine continues 227 with the measuring 228 of the peak velocity which will be stored in the memory register "A". The preprogrammed value of atrio-ventricular delay is read 229 from the memory and the microprocessor initiates the A-V delay 230. In the meantime the DMI is stopped 231 because there is no further Doppler wave expected. The content of memory register "E" is divided by the content of memory register "A" 232 in order to obtain the ratio of peak velocities of early diastolic and atrial filling. The same ratio of the former heart beat is read 233 from the memory register Eo/Ao. If the E/A ratio of the latter heart beat is significantly smaller 235 from the E/A ratio of the former heart beat, this means that the high rate ischemia is provoked and the angina pectoris may occur. The preprogrammed constant K1, read 234 from the memory, determines what is the significant change of the E/A ratio. In the case of high pacing rate ischemia, the A-V delay will be prolonged 236

in order to provoke Wenckebach tracking rate response. It is known from the art that other maximum tracking rate responses are possible like 2:1 block as well as the fallback rate pacing. If there is no change in E/A ratio the value of latter E/A ratio is stored 237 in the memory register Eo/Ao for the future comparison with the next heart beat. The A-V delay waiting loop is entered 238 and the pacing pulse will be generated 239, 202 at the end. In the case of atrial fibrillation 226, the pacemaker will be programmed 240 to the rate of responsive mode. The DMI is stopped 241 and the preprogrammed constant K2 is read 242 from the memory. Peak early diastolic velocities are read 243 from the register "Eo" for the former heart beat and from the register "E" for the latter heart beat. The high rate pacing induced ischemia will be always preceded by the drop of the early diastolic filling velocity. Therefore the protection algorhythm from high rates especially for patients with angina pectoris must be incorporated. The constant K2 determines the amount of beat to beat change of the peak velocity E. If the velocity E of the latter beat is significantly lower 244 than the velocity Eo of the former beat, the escape interval i.e. the pacing interval in rate responsive mode must be increased 245. The latter peak velocity E is stored 246 in register Eo for the future comparison with the next beat peak velocity. After that the pacing impulse may be generated 247. If there is no significant change 244 in peak velocity, the value E is stored 248 in register "Eo" for future comparison with next beat peak velocity. The programmed rate responsive slope function is read 249 from the memory and according to the rate responsiveness sensor value stored in the counter "RR" 250, the new escape interval is calculated 251 and the pacing impulse is generated 252.

If there had been no first wave detected 209 and the escape interval was completed 212, the DMI is stopped 254. The microprocessor "knows" whether the expected Doppler wave had to be the consequence of the paced or the sensed beat. If this was a sensed beat 255, the flag which is influenced by the ventricular tachycardia and fibrillation detection algorhythms is read 256. If the fibrillation or ventricular tachycardia was detected 257, it is the life threatening arrhythmia and the anti-tachycardia subroutine is started 258 which may be defibrillation in implantable defibrillator or any other kind of anti-tachy therapy with an implantable device. If there was not tachycardia detected 257, the missing Doppler wave may have been caused by the lack of Doppler circuit sensitivity. Therefore the Doppler circuit sensitivity is increased 259. If this was a paced beat 255, the missing Doppler wave may have been caused by the loss of capture. Therefore the pacing output energy is reprogrammed to the higher step 260 and the pacing pulse is generated 261. Logic diagram connectors are designated by 240, 247, 252, 253 and 261. Disclosed logic diagram illustrates the function of a pacemaker only for the example of basic idea. The function of described invention in an external temporary pacemaker and in an implantable defibrillator was not particularly disclosed because the basic principle is the same with appropriate modifications as it is known in the art. For instance, there is no Figure in this disclosure which shows the intracardiac spring lead for implantable defibrillator, but it is obvious that Doppler transducers may be incorporated in such a lead keeping the right design rules in mind.

In the embodiment of Fig. 15 there is disclosed a detailed axial cross-section of the lead and the flow measurement transducer made of piezo film, either from the lead from Fig. 5 or from the distal transducer of the lead from Fig. 6. Within the plastic body 280 there is a lead conductor 281 having a stylet channel 282 which connects the pacing electrode at the distal end (not shown) with the connector at the proximal end (not shown) of the lead. The piezoelectric transducer 283 made of material such as Kynar Piezo Film (Penwalt Corp.), mounted coaxially on the plastic body 280, has two electrodes 284 and 285 i.e. thin metallized layers. The transducer electrode 284 is electrically connected with the pacing lead conductor 281 by means of the connection wire 286 and electrical joints 287 and 288. The transducer electrode 285 is electrically connected with another lead conductor 289 by means of another connection wire 290 and electrical joints 291 and 292. An ultrasonic lens 293 is fitted and glued by the transducer. The lens 293 is of the form of a tapered ring and represents an essentially conical ultrasonic lens. At the end opposite to the lens of the transducer there is a backing 294 glued onto the electrode 284. The backing 294 is built of either an air equivalent material such as expanded plastic or of an ultrasound absorbing material such as synthetic resin filled with metal powder. This backing is of such a tapered form that it does not obstruct the indwelling procedure. The lens 293, the transducer 283 and the backing 294 are covered with a thin sheath 295 of electrically insulating material not thicker than 5% of the ultrasound wavelength used.

The disclosed lead assembly comprises helically wounded coaxial lead conductors with a stylet channel which is the technology used in leads for permanent implantation. Simpler design is possible for temporary cardiac leads using ordinary insulated copper wires in a plastic tube. The plastic body may consist of multiple insulation sheaths i.e. plastic tubes between and over the lead conductors.

Another embodiment of the Doppler measurement device mounted at the point of interest on a cardiac pacing lead is the example comprising plate transducers. The said transducers are mounted on a tilted backing made of very ultrasound reflective material. The transducers are pairwise tilted out of the axial symmetry direction so that their directivities intersect, thus creating two sensitive volumes for continuous wave Doppler measurements. Unlike axially symmetric ultrasound sensitive volumes described above, this embodiment has two distinct sensitive volumes positioned at 180° across the catheter axis. The design, applicable for temporary pacing leads, is illustrated in Fig. 16 to 19.

Fig. 16 is an axial cross-section through a bipolar pacing lead comprising plate transducers for velocity measurement, mounted at an appropriate distance from the lead tip. The lead comprises:

- a plastic hollow catheter body 301 within which there are pacing-sensing lead conductors 302 and 303 which are electrically connected to the corresponding electrodes (not shown) at their distal end, and to the corresponding connector pins (not shown) at their proximal end,
- a backing 304 made of air equivalent material (hard expanded plastic) in form of a double truncated cone,
- a multitude of plate piezoelectric transducers 305 and 306 glued to a surface of the backing 304, the transducers having thin metallized layers which are transducer electrodes 310, 311, 312, 313,
- additional two piezoelectric plate transducers (not shown) to achieve circular symmetry,
- additional lead conductor 326 for connection of transducers, said conductor being bifurcated in two conductors 318 and 328,
- additional lead conductor 327 for connection of transducers, said conductor being bifurcated in two conductors 320 and 329.

The connection conductor 318 is conductively glued or soldered by means of electrical joint 314 to the transducer electrode 310, thus lead conductor 326 being the first pole of transducer 305. The connection conductor 328 is connected to the adjacent transducer (not shown) in the same manner and for the same purpose. The connection conductor 320 is conductively glued or soldered by means of electrical joint 316 to the transducer electrode 312, thus lead conductor 327 being the first pole of transducer 306. The connection conductor 319 is conductively glued or soldered by means of electrical joint 315 to the transducer electrode 311, as well as by means of electrical joint 324 to the lead conductor 303, thus lead conductor 303 being the second pole of transducer 305. The connection conductor 321 is conductively glued or soldered by means of electrical joint 317 to the transducer electrode 313, as well as by means of electrical joint 325 to the lead conductor 303, thus lead conductor 303 being the second pole of transducer 306.

Transducers assembly is covered by means of an insulating sheath (membrane) 330 of thickness less than 5% of the wavelength of the dominant used ultrasound frequency covering the whole device.

Fig. 17 is the transversal cross section F-F as indicated in Fig. 12. The device is shown without the insulating membrane 330. In this illustration one can see all the four plate transducers 305, 306, 405 and 506 having thin metallized layers 310, 312, 410 and 512 respectively. The opposite metallized layers cannot be seen from disclosed view. These transducers are arranged in transmitter-receiver pairs, i.e. 306 and 506 are a pair and 305 and 405 are a pair. The paired transducers are tilted towards each other as can be seen by the perspective view of the transducer plates. The connection conductor 329 is connected to the transducer electrode 410 by means of the electrical joint 414, thus conductor 327 being the first pole of transducer 405. The connection conductor 328 is connected to the transducer electrode 512 by means of the electrical joint 514, thus conductor 326 being the first pole of transducer 506. The connection conductor 521 is connected to the transducer 506 through another metallized layer (not shown) by means of the electrical joint 517, and to the lead conductor 303 by means of the electrical joint 525, thus conductor 303 being the second pole of the transducer 506. The connection conductor 419 is connected to the transducer 405 through another metallized layer (not shown) by means of the electrical joint 415, and to the lead conductor 303 by means of the electrical joint 424, thus conductor 303 being the second pole of the transducer 405. In disclosed wiring assembly the lead conductor 303 is common for all four transducers. If the transmitter circuit is connected to lead conductor 326 and the receiver circuit to lead conductor 327 (or vice versa), transducers 305 and 506 will be ultrasonic transmitters while transducers 306 and 405 will be ultrasonic receivers (or vice versa). The sideways tilt results in the overlapping of the directivity characteristics of the said pairs of transducers as it is shown in following figures. The perpendicular cross sections through the sensitivity areas at the level of section F-F are shown as shaded areas 601 and 602.

Fig. 18 is a perspective drawing of the side view of the lead from Fig. 16 and 17 without the covering insulation sheath 330 in order to illustrate

the positions and tilts of the piezoelectric transducers 305 and 405 as well as the ultrasound directivity characteristics of the two transducers. The transducers are glued onto the said air-equivalent backing 304. Their metallized layer electrodes are conductively glued or soldered by means of electrical joints 314 and 414 to connection conductors 318 and 329 respectively. The connecting wires of other said transducers and the rest of the connecting wires of transducers 305 and 405 are not shown. The body of the catheter 301 holds all the measuring devices, but can induce clutter into the ultrasonic measurement beams 340 and 440. The beams are illustrated by their boundaries; boundaries 441 and 442 for transducer 405 and beam 440, and boundaries 341 and 342 for transducer 305 and beam 340. Directivity axis 343 is for transducer 305 and beam 340 as well as directivity axis 443 for transducer 405 and beam 440. The overlapping region between the beams 440 and 340 is indicated as well 600. When the two transducers 305 and 405 act as a Doppler transmitter-receiver combination the overlapping region 600 is the sensitive area of the blood flow velocity measurement. Disclosed boundaries are drawn for illustration only and they can be exactly defined as a surface of specified ultrasonic field intensity.

Fig. 19 illustrates the situation of Fig. 18 only shown from an angle by 90° around the catheter axis different. This illustration shows that, while there is an overlapping zone between pairs of transducers as shown in Fig. 18, there is a dead zone of sensitivity at positions at 90° around the axis to the said sensitive area positions. Two opposite sensitivity volumes 600 and 603 are disclosed. The former is the geometrical intersection of ultrasonic beams of transducers 305 and 405, while the latter is the geometrical intersection of ultrasonic beams of transducers 506 and 306. Disclosed transducers assembly produces two ultrasonic sensitive volumes in order to obtain more reliable blood velocity measurement. However, simpler design is possible with only two transducers producing one sensitive volume.

While specific embodiments of present invention have been described, it should be understood that these embodiments are described for purposes of illustration only. The foregoing description is not intended in any way to limit the scope of the present invention. Rather is the intention that the scope of the invention be limited only as defined in the appended claims.

Claims

1. A cardiac electrotherapy system comprising a blood flow velocity measurement cardiac pacing lead, electronic circuitry for cardiac electrotherapy and electronic circuitry for blood flow velocity measurement, timing and processing of the velocity data, said system comprising means for a ventricular pacing synchronous with atrial contractions with the use of a single said lead and means for a rate responsive pacing, wherein said means are controlled by means of processing of the diastolic filling waveform of blood flow through a cardiac valve or along a blood vessel.

2. The cardiac electrotherapy system according to claim 1 comprising means for measurement of the blood velocity during determined time interval synchronized with the ventricular electrical activity, said interval occurring with a determined delay after ventricular activity.

3. The cardiac electrotherapy system according to claim 1 or 2, comprising means for discrimination between early diastolic filling wave (31) and atrial filling wave (33, 34), as well as means for measurement of peak velocities (E, A) of both waves and calculation of time integrals of both waves.

4. The cardiac electrotherapy system according to claim 3, comprising means for ventricular pacing (36) synchronous with atrial filling wave (34) detected by said circuitry, whereby ventricular pacing maintains the physiologic atrioventricular delay.

5. The cardiac electrotherapy system according to claim 3 or 4, comprising means for calculation of ratio of the peak velocities (E, A) of said filling waves and calculation of ratio of the time integrals of said filling waves.

6. The cardiac electrotherapy system according to claim 5, comprising means for beat to beat comparison of said ratios, and means for detection of consecutive decrease of said ratios indicating the high rate induced ischemia, as well as means for successive decrease of ventricular pacing rate in the case of high rate ischemia in such a way as to prevent the high rate induced cardiac ischemia.

7. The cardiac electrotherapy system according to any of claims 1 to 6, comprising means for detection of atrial fibrillation i.e. the disappearance of said atrial filling wave (33, 34) as well as means to maintain the rate responsive ventricular pacing while the atrial fibrillation is sustained, and means to revert to synchronous ventricular pacing upon the occurrence of said atrial filling wave.

8. The cardiac electrotherapy system according to any of claims 3 to 7, comprising means for measurement of the time interval (QE) between the ventricular pacing impulse (43) and the said early diastolic wave (46), said interval being the sensor for rate-responsive pacing in such a way that the pacing rate increases whenever the said interval decreases and vice versa.

9. The cardiac electrotherapy system according to claims 3 to 7, comprising means for measurement of the time duration (RFP) of said early diastolic wave (42), said duration being the sensor for rate-responsive pacing in such a way that the pacing rate increases whenever the said duration decreases and vice versa.

10. The cardiac electrotherapy system according to any of claims 3 to 7, comprising means for measurement of the first derivative (dE/dt) at the onset of said early diastolic wave (42), said derivative being the sensor for rate-responsive pacing in such a way as that the pacing rate increases whenever the said derivative increases and vice versa.

11. The cardiac electrotherapy system according to any of claims 3 to 7, wherein said peak velocities (E, A) are sensors for rate-responsive pacing in such a way as that the pacing rate increases whenever either of the said measured diastolic filling velocities increase and vice versa.

12. The cardiac electrotherapy system according to any of claims 3 to 7, comprising means for rate responsive pacing in such a way as to measure and calculate the rapid filling fraction and to increase the pacing frequency whenever the said fraction decreases and vice versa.

13. The cardiac electrotherapy system according to any of claims 3 to 12, comprising means for detection of missing ventricular contractions i.e. the disappearance of said early diastolic waves (31, 42), and means to discriminate if missing contractions are caused by the loss of capture or by the ventricular fibrillation or tachycardia.

14. The cardiac electrotherapy system according to any of claims 3 to 13, comprising means for detection of sudden decrease of said measured peak velocity (E_p) of the said early diastolic wave (42, 46) in single beat, said sudden decrease indicating that said single beat is the ventricular premature beat.

15. The cardiac electrotherapy system according to claim 3, comprising means for detection of sudden decrease of said measured peak velocity (E_p) of the said early diastolic waves (42, 46) in series of heart beats, said sudden decrease indicating that said series of beats is the ventricular tachycardia.

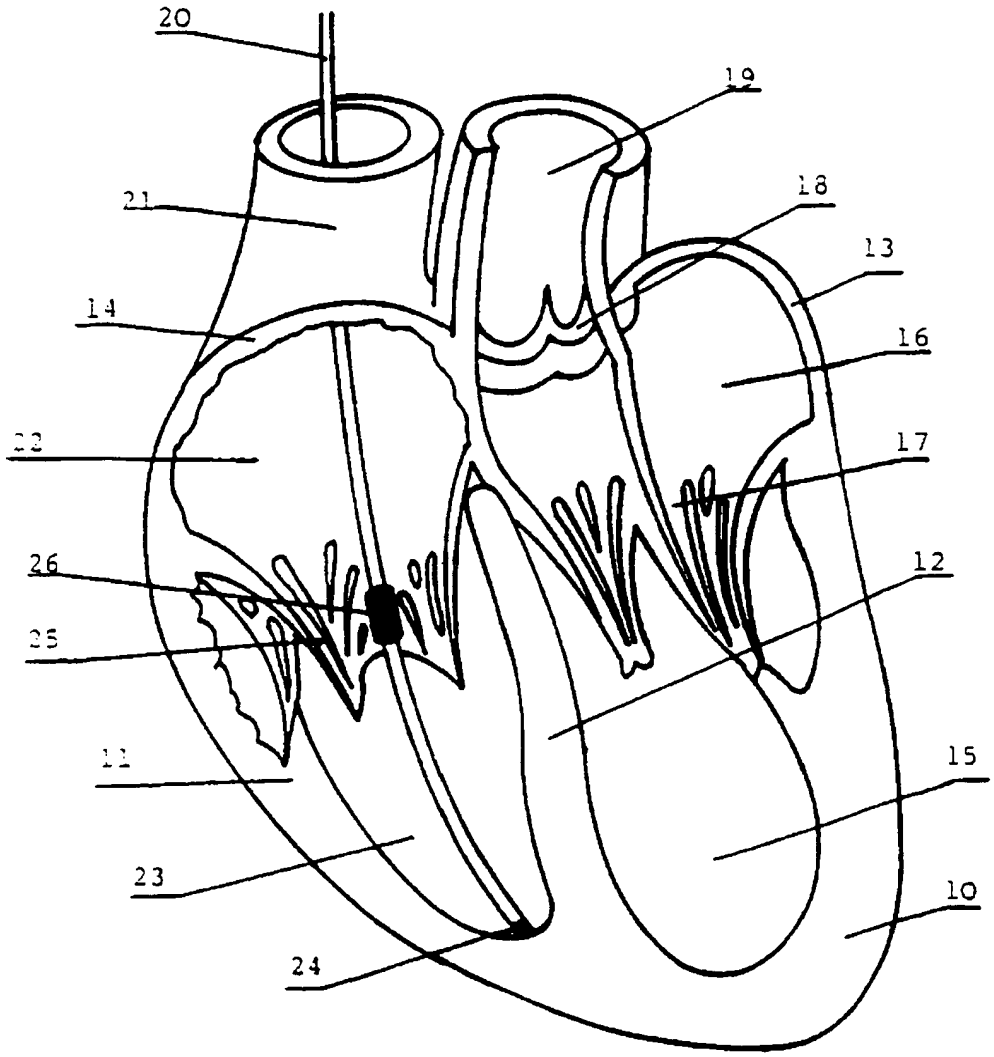

FIG. 1

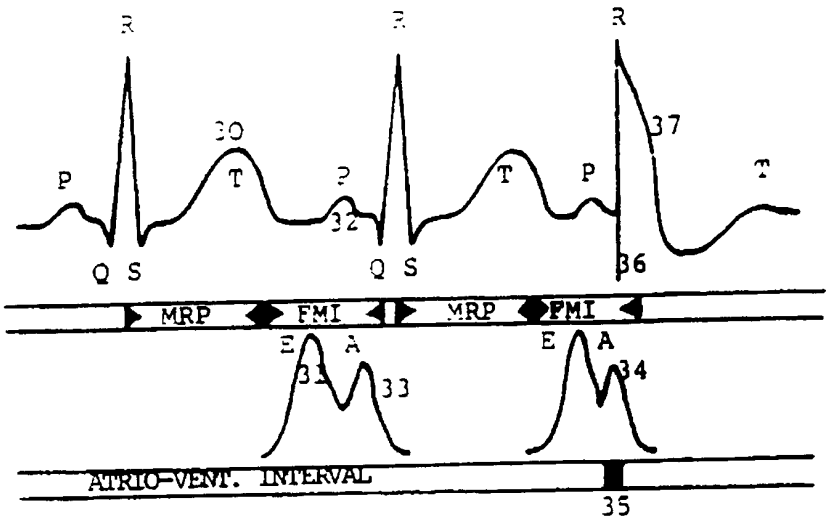

FIG. 2

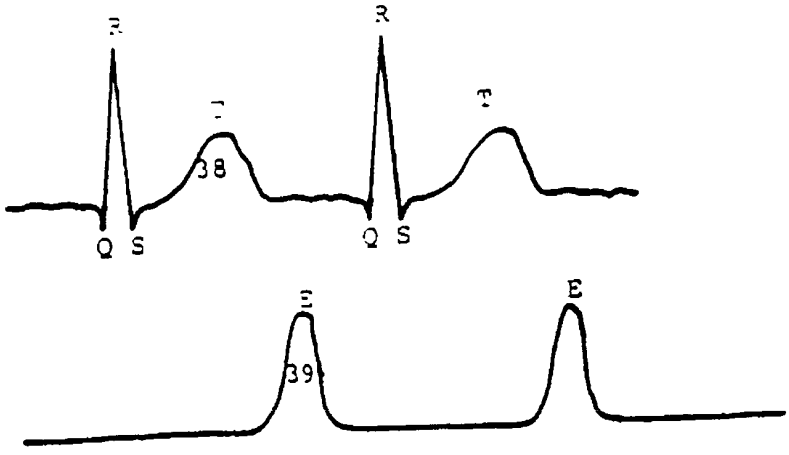

FIG. 3

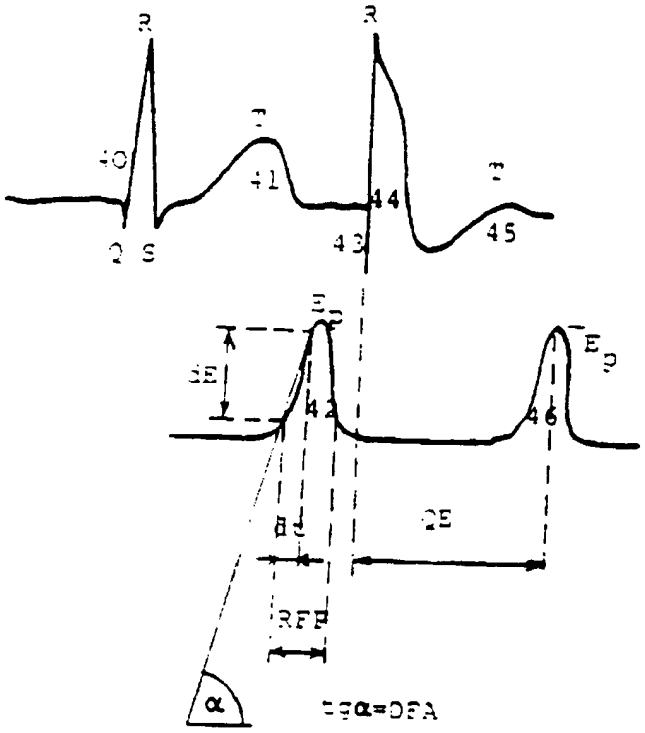

FIG. 4

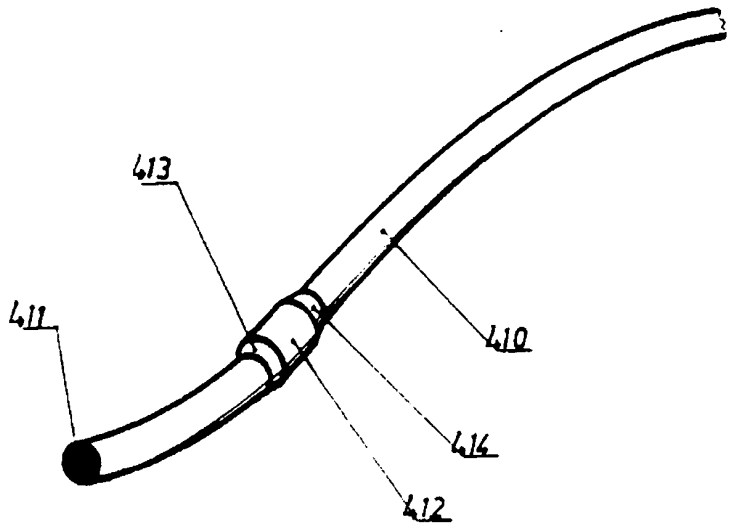

FIG. 5

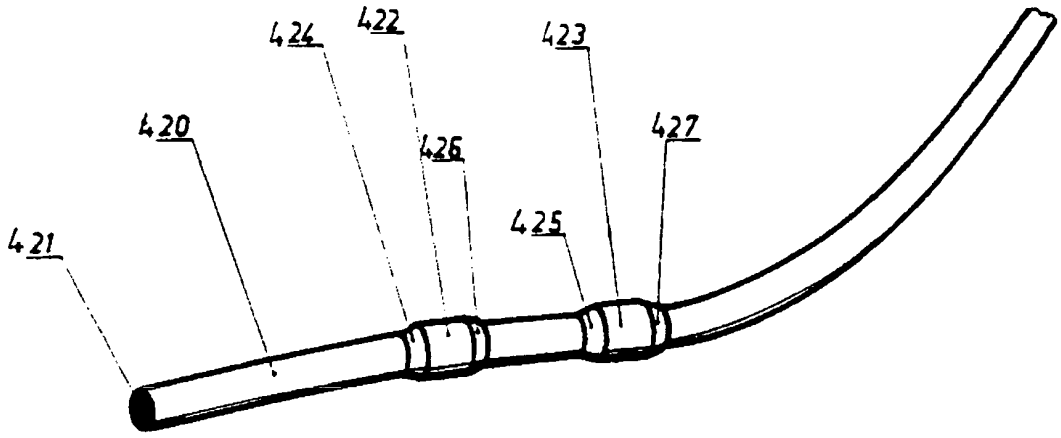

FIG. 6

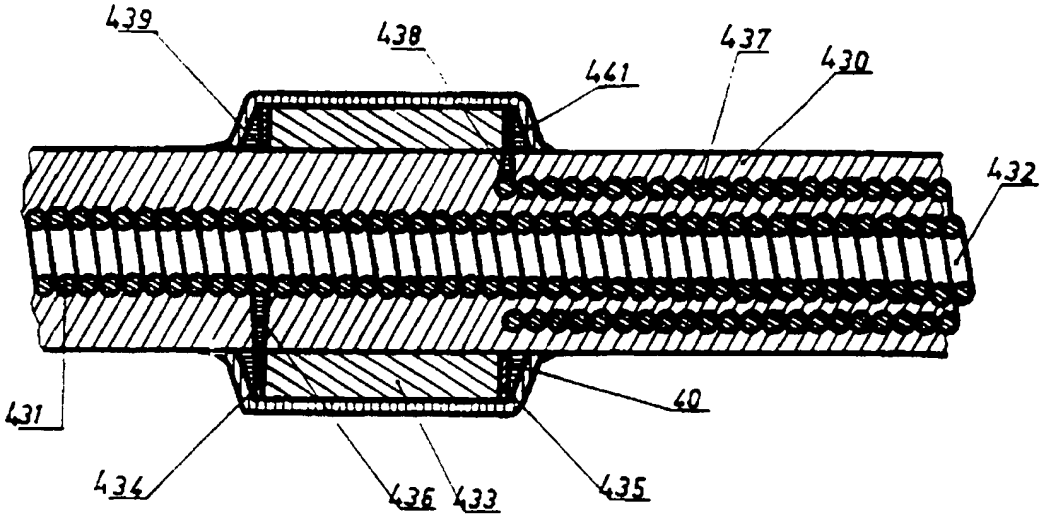
439
438
441
437
430
432
40
431
434
436
433
435

FIG. 7

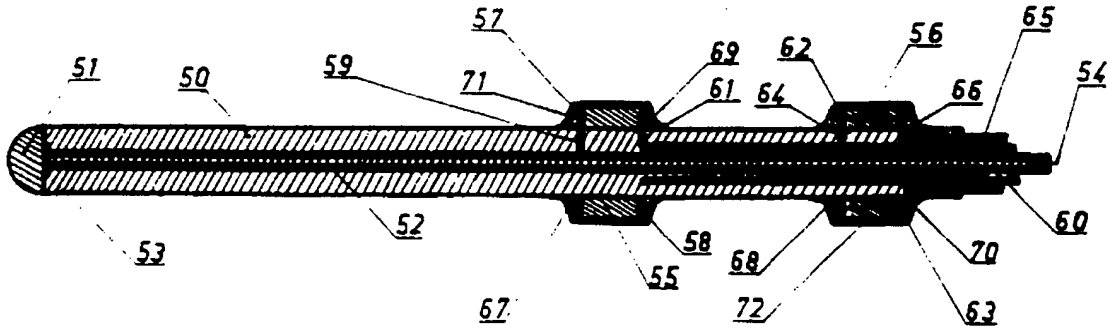
57
51
50
59
71
69
62
56
65
61
64
66
54
52
58
60
53
55
68
70
67
72
63

FIG. 8

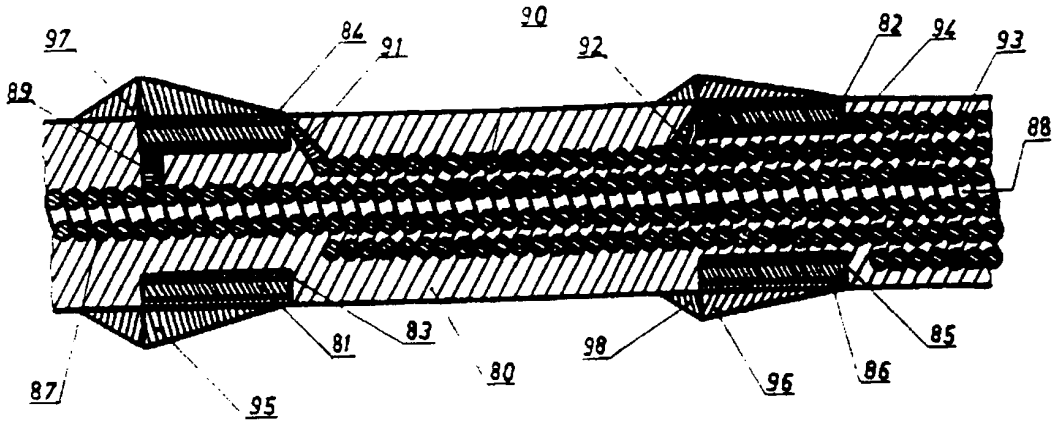

FIG. 9

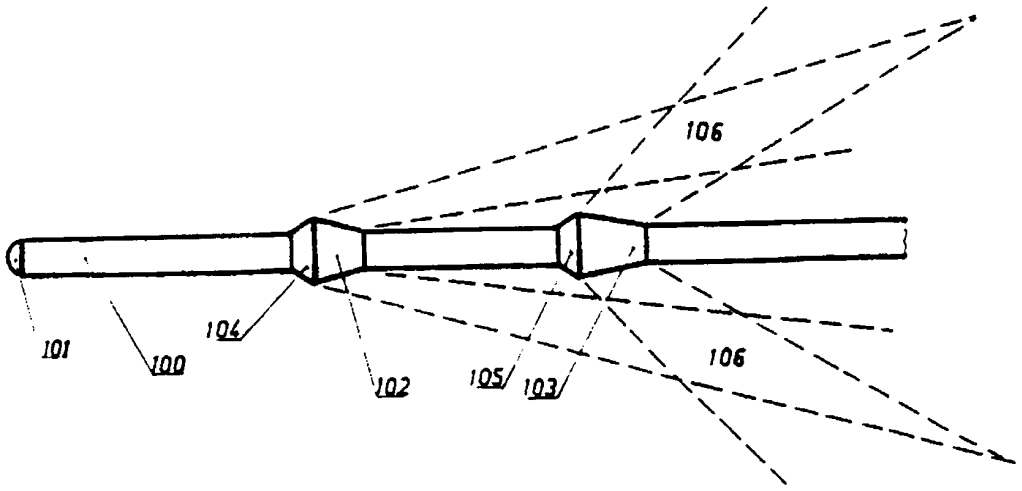

FIG. 10

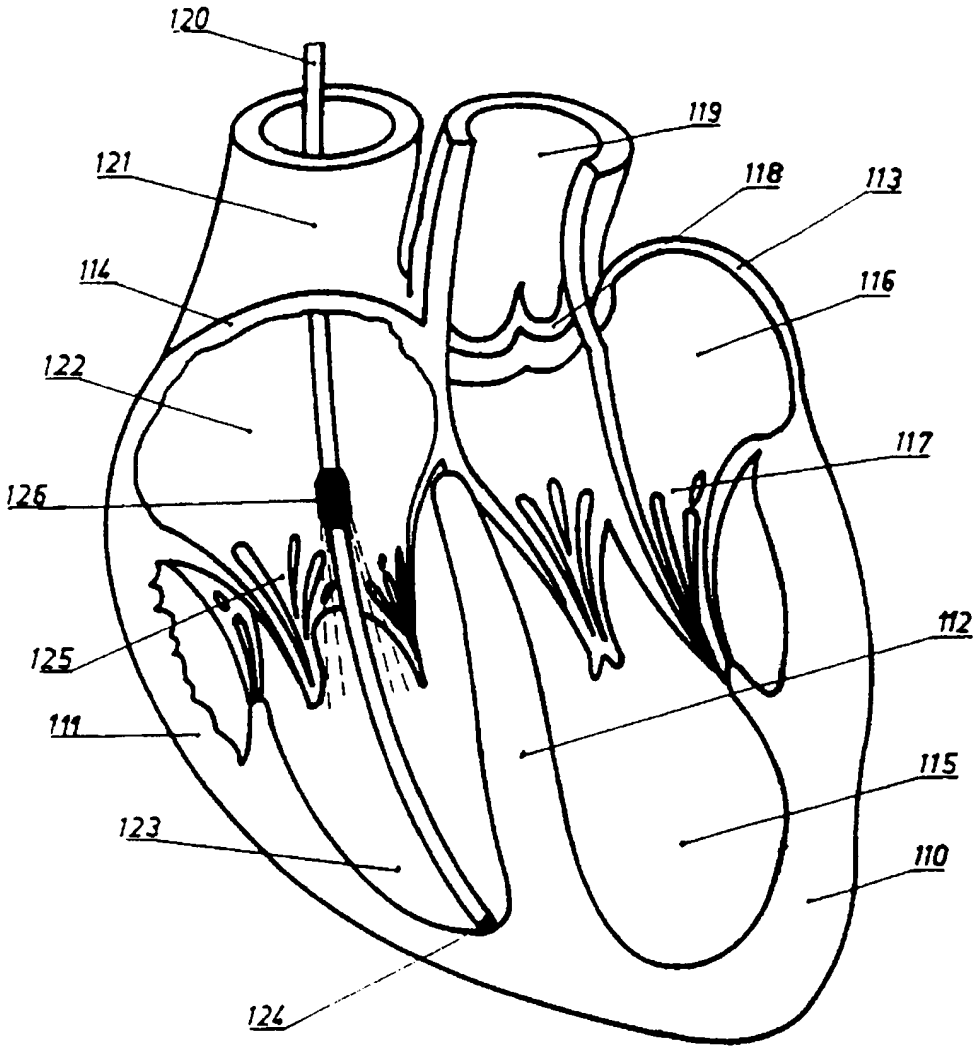

FIG. 11

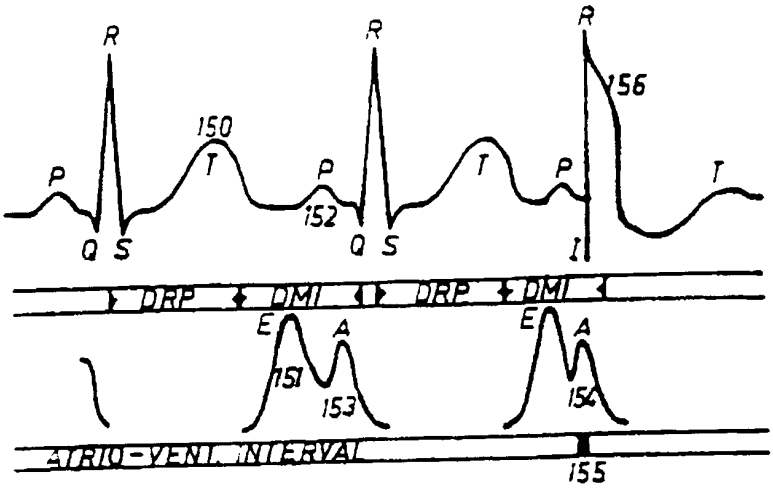

FIG. 12

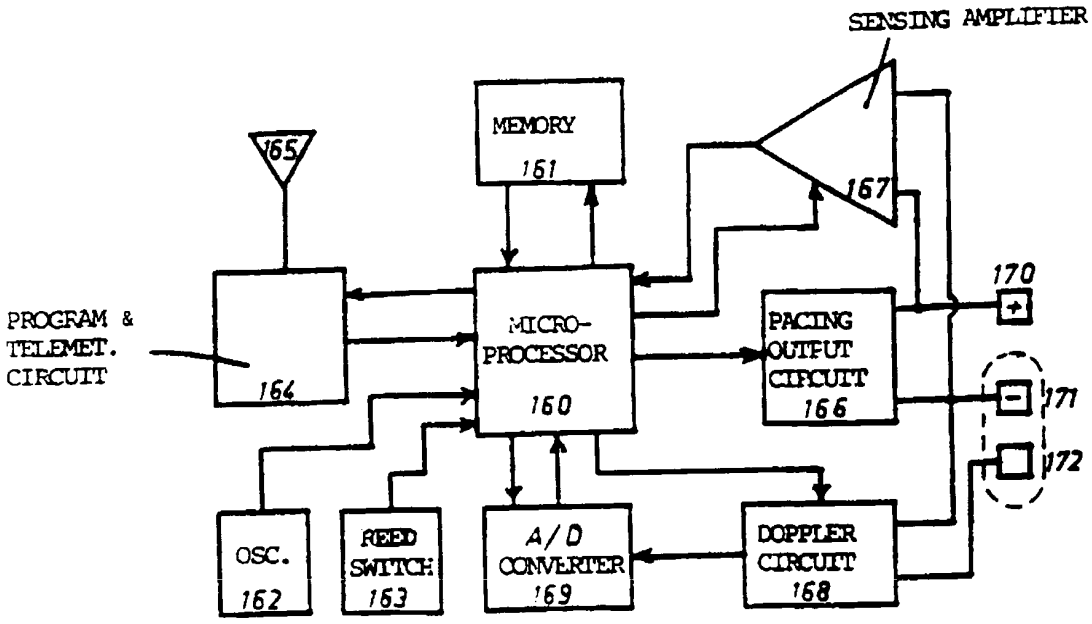

FIG. 13

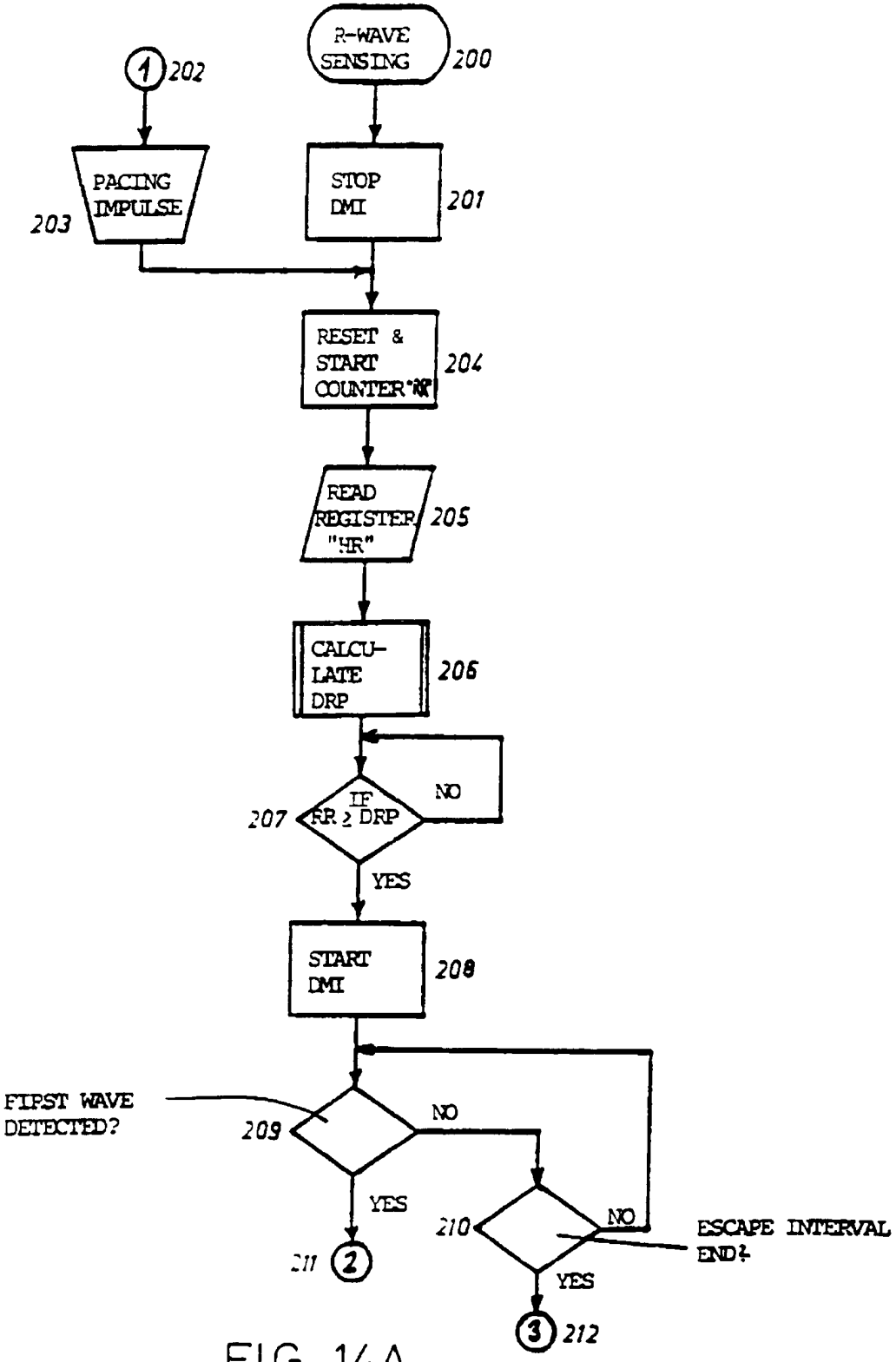

FIG. 14A

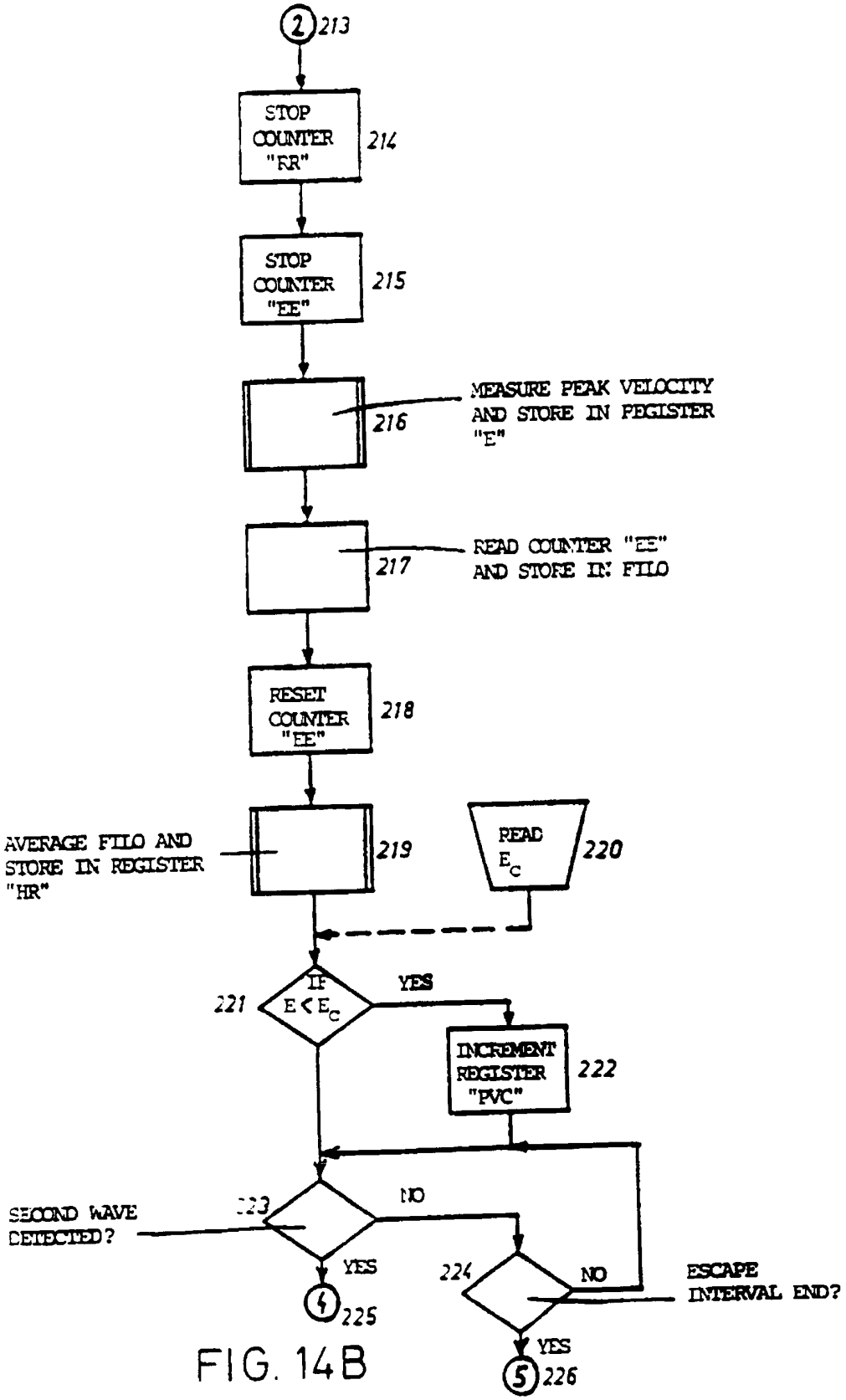

FIG. 14B

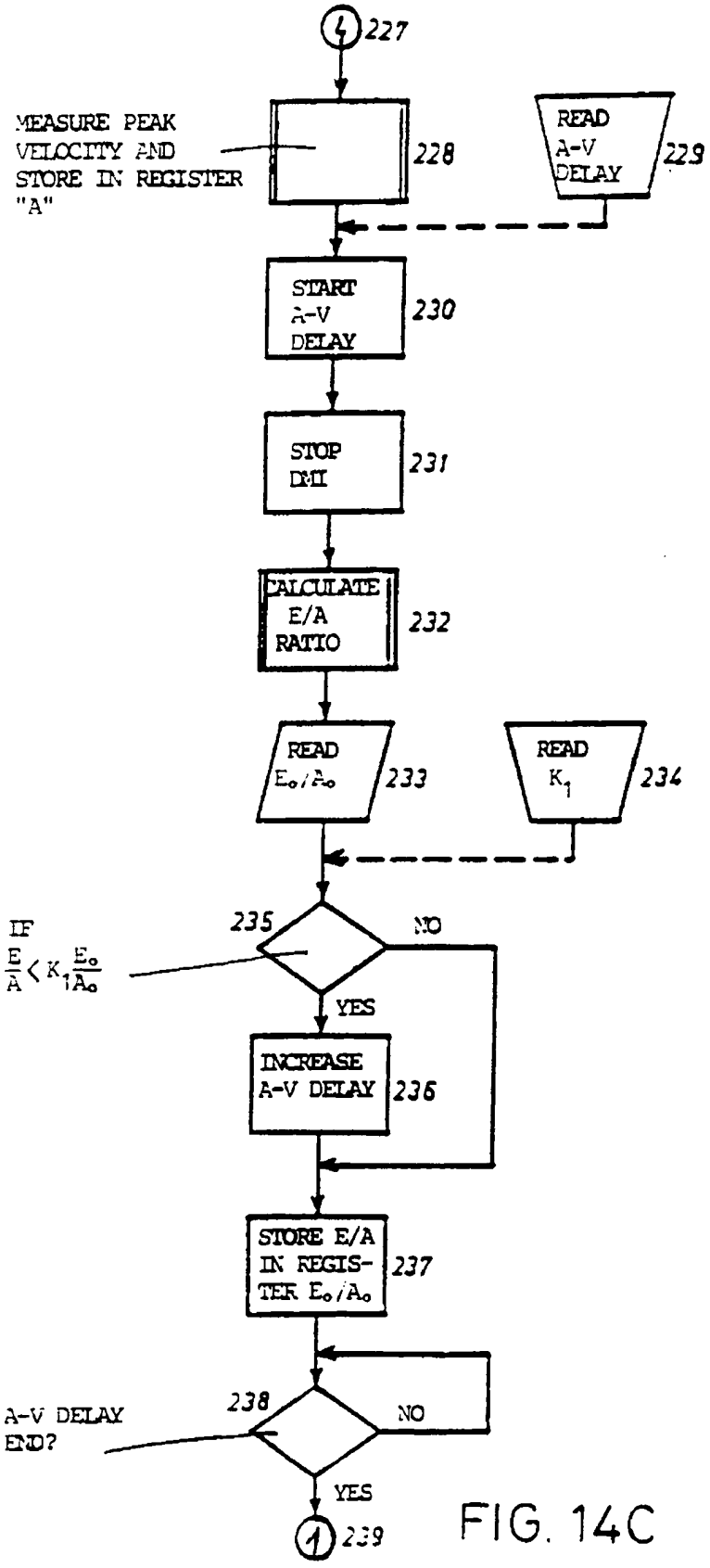
227
MEASURE PEAK VELOCITY AND STORE IN REGISTER "A"
228
READ A-V DELAY
229
START A-V DELAY
230
STOP DMI
231
CALCULATE E/A RATIO
232
READ E_o/A_o
233
READ K_1
234
IF $\frac{E}{A} < K_1 \frac{E_o}{A_o}$
235
NO
YES
INCREASE A-V DELAY
236
STORE E/A IN REGISTER E_o/A_o
237
A-V DELAY END?
238
NO
YES
1
239

FIG. 14C

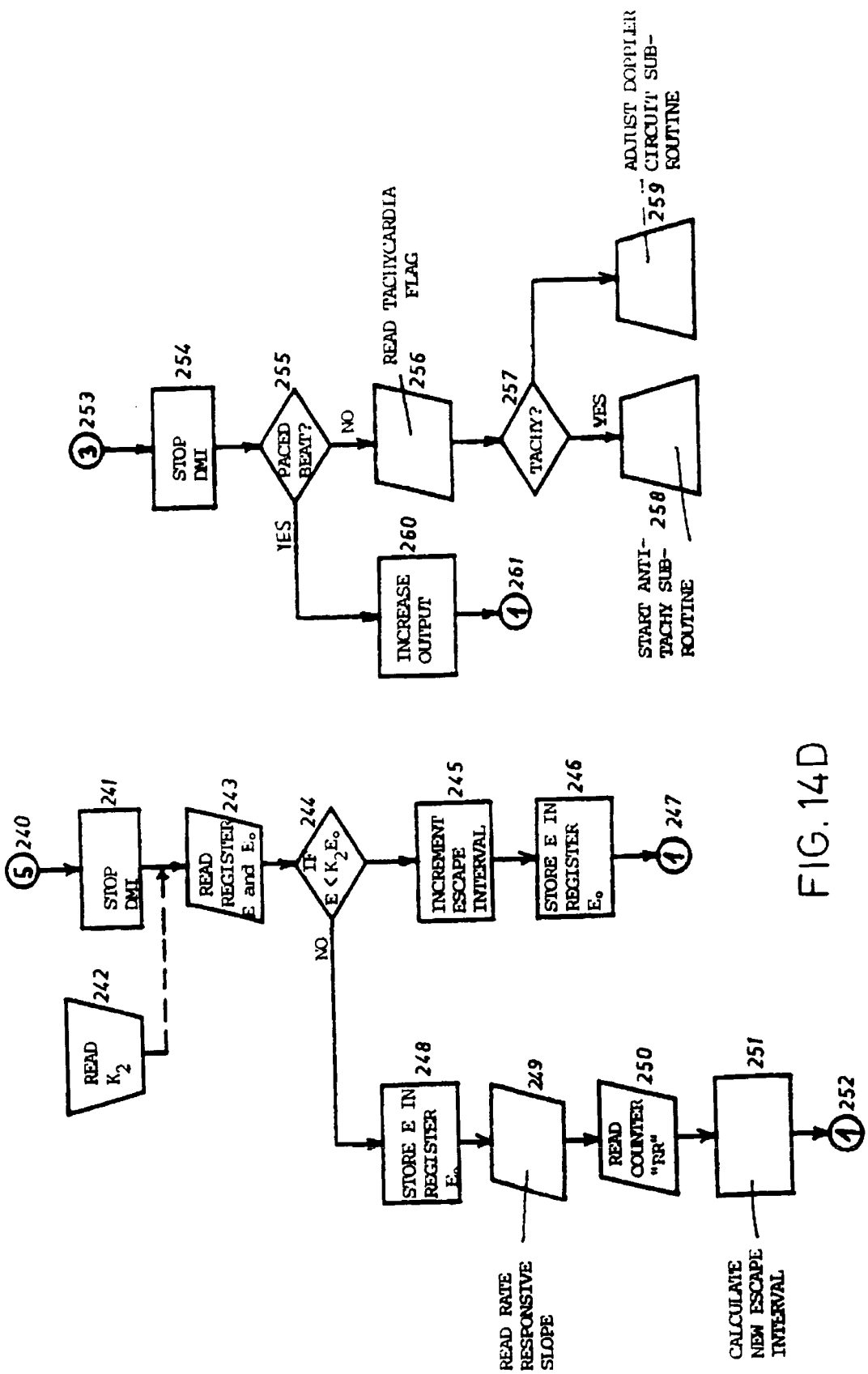

FIG. 14D

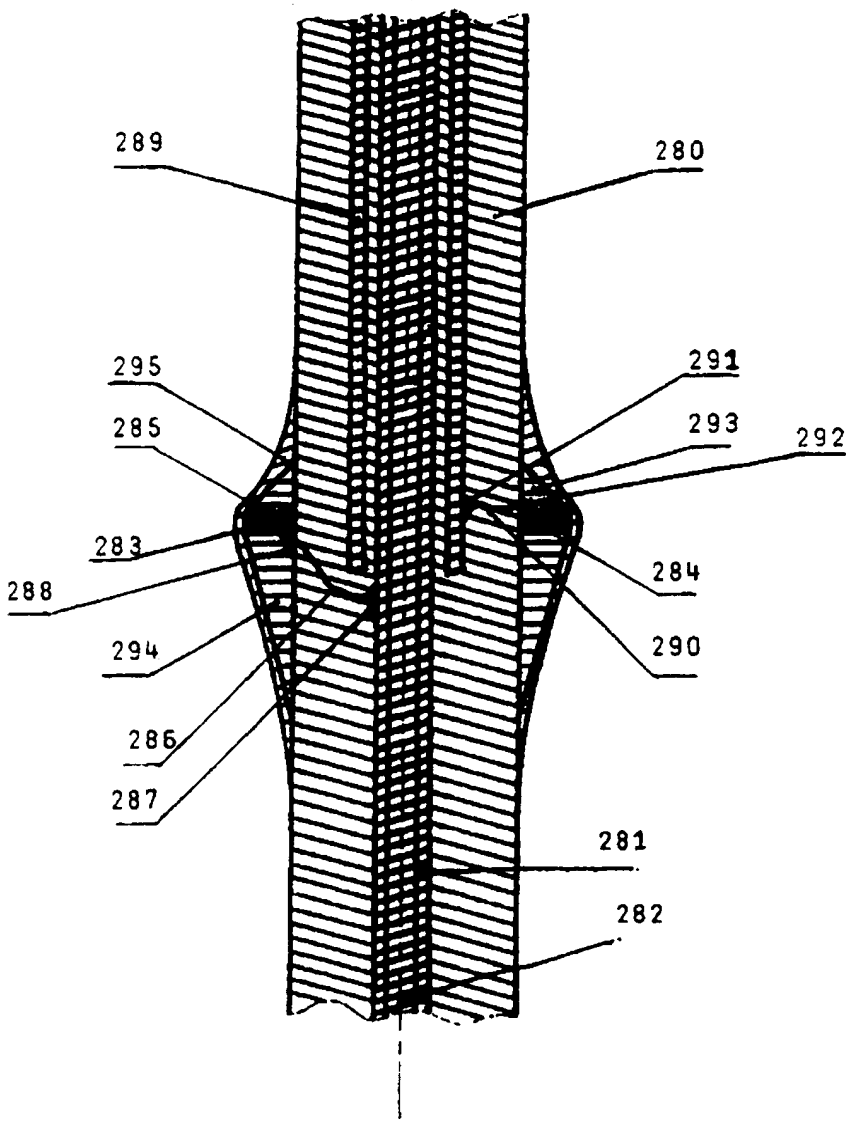

FIG. 15

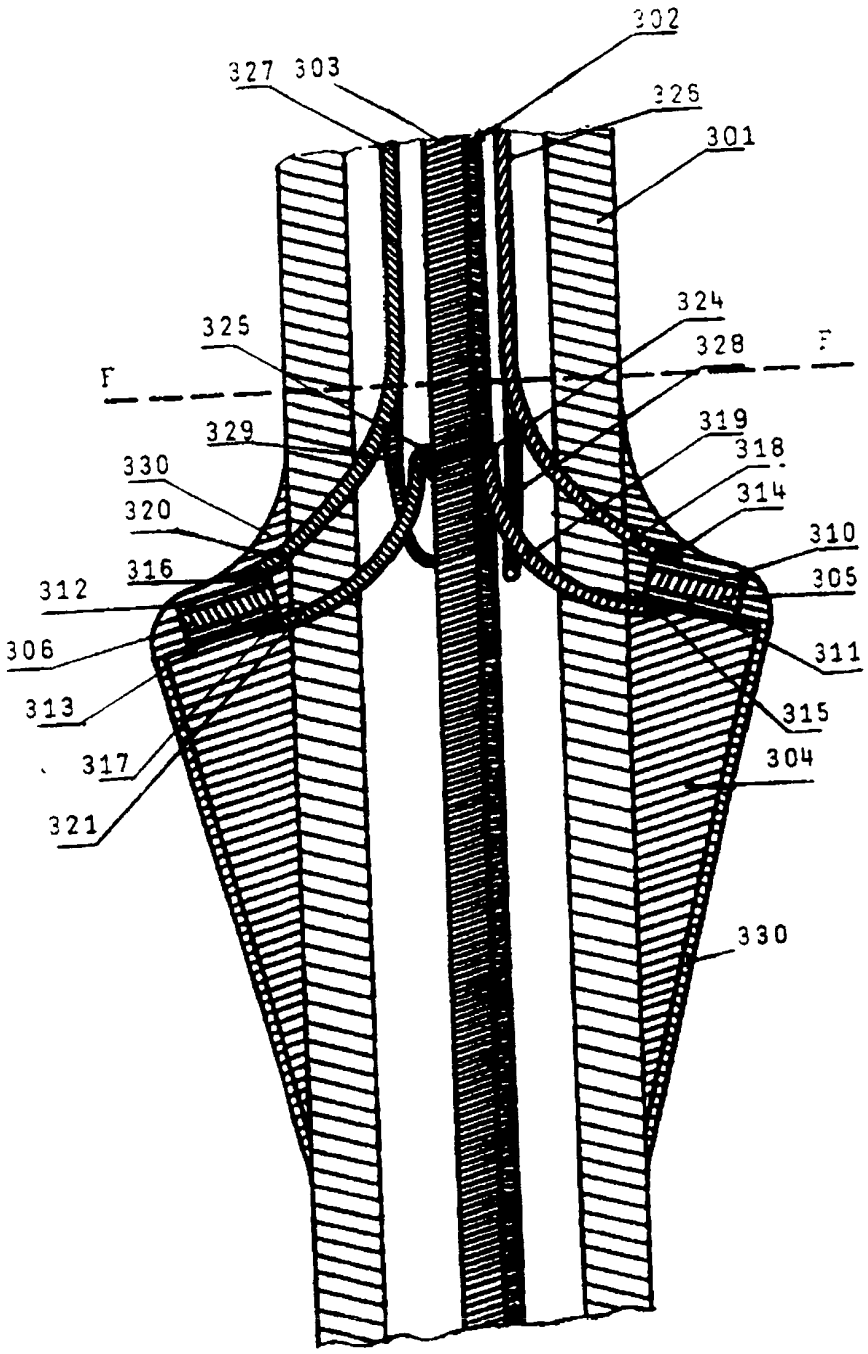

FIG. 16

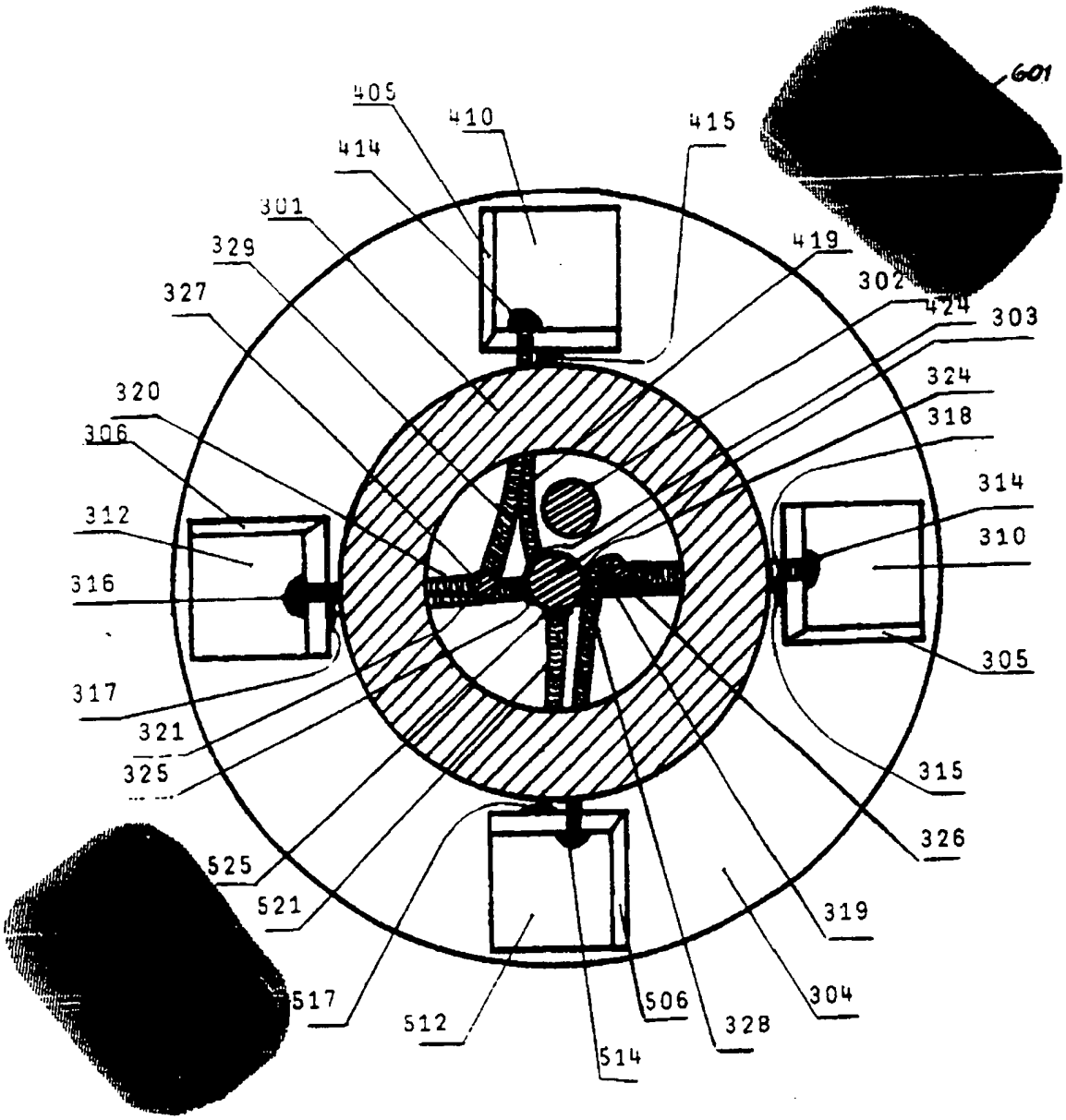

FIG. 17

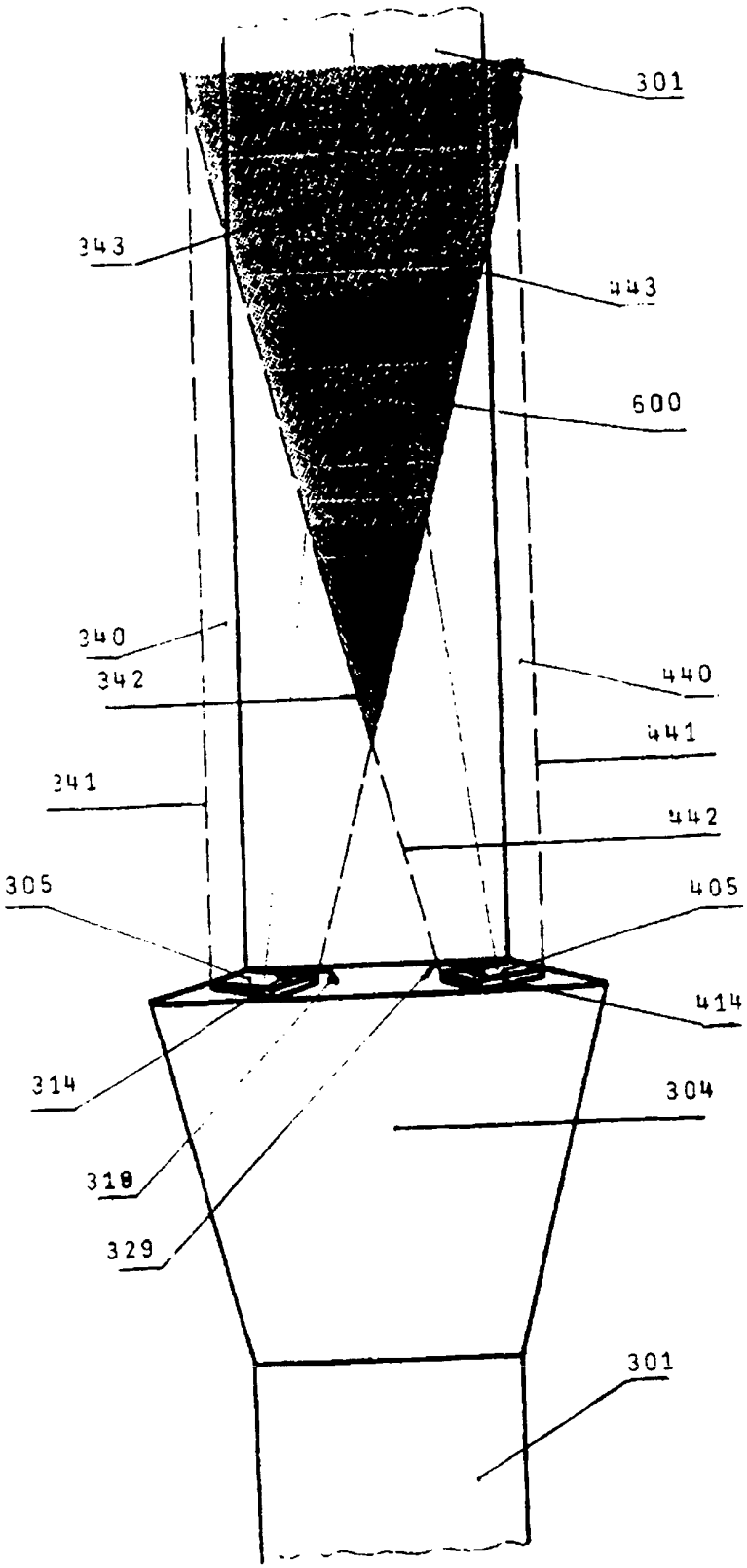

FIG. 18

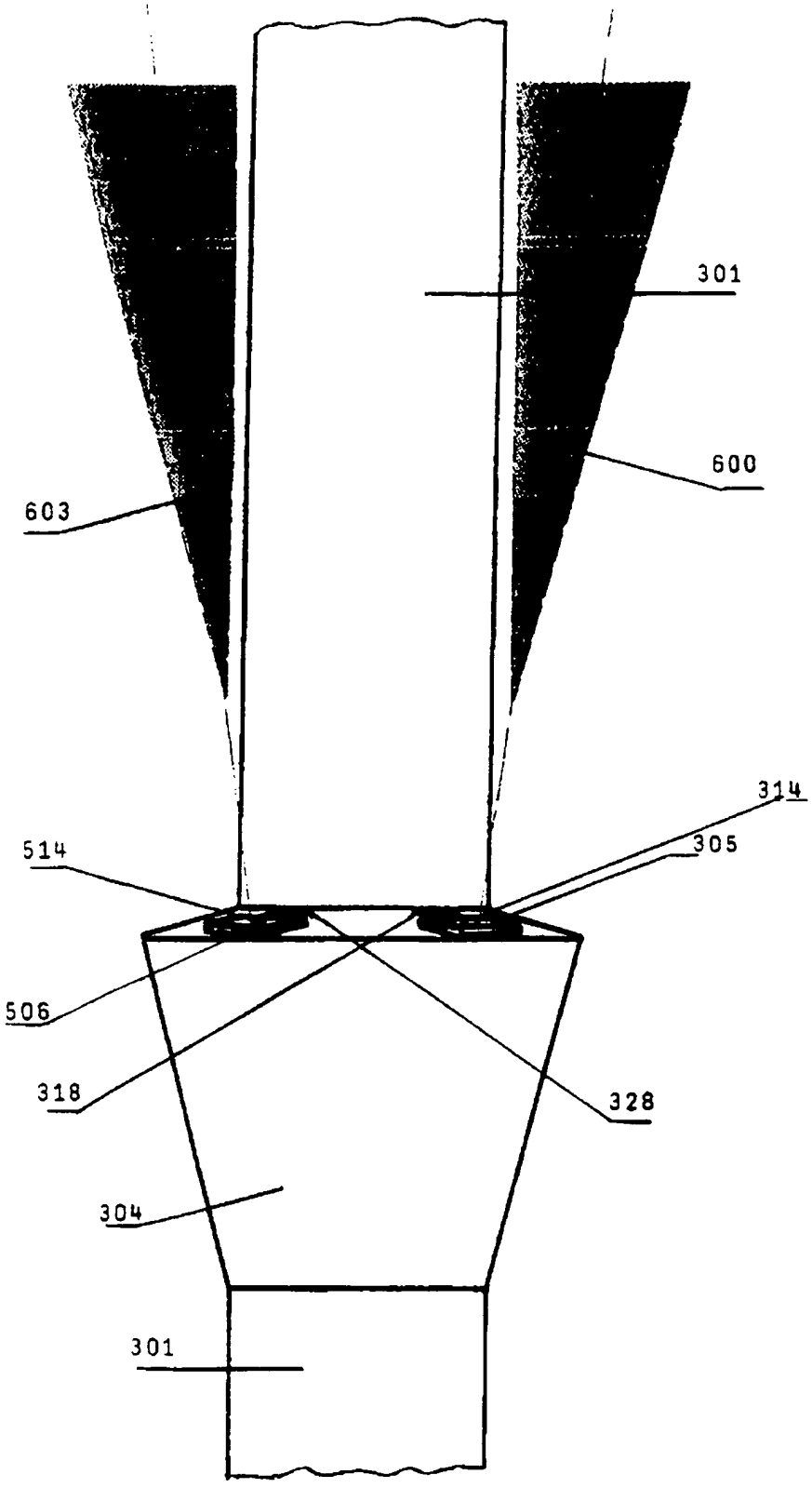

FIG. 19

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 474 958 A3**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **91104561.5**

(51) Int. Cl.5: **A61N 1/365**, A61B 8/06

(22) Date of filing: **22.03.91**

(30) Priority: **11.09.90 YU 1717/90**

(43) Date of publication of application:
18.03.92 Bulletin 92/12

(84) Designated Contracting States:
DE FR GB IT NL

(88) Date of deferred publication of the search report:
24.06.92 Bulletin 92/26

(71) Applicant: **Ferek-Petric, Bozidar**
Sovinec 17
YU-41000 Zagreb, Croatia(YU)
Applicant: **Breyer, Branco, Dr.**
Prilaz JA 79
YU-41000 Zagreb, Croatia(YU)

(72) Inventor: **Ferek-Petric, Bozidar**
Sovinec 17
YU-41000 Zagreb, Croatia(YU)
Inventor: **Breyer, Branco, Dr.**
Prilaz JA 79
YU-41000 Zagreb, Croatia(YU)

(74) Representative: **Blumbach Weser Bergen Kramer Zwirner Hoffmann Patentanwälte**
Radeckestrasse 43
W-8000 München 60(DE)

(54) Cardiac electrotherapy system.

(57) In a cardiac electrotherapy system comprising a blood flow velocity measurement cardiac pacing lead, means for ventricular pacing synchronous with atrial contractions and means fo a rate responsive pacing, pacing is controlled by means of processing of the diastolic filling waveform of blood flow through a cardiac valve.

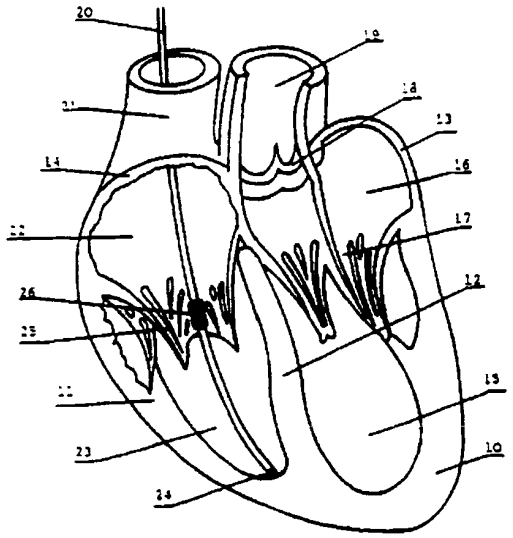

FIG. 1

EP 0 474 958 A3

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 10 4561

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y,D	EP-A-0 311 019 (SIEMENS-ELMA AB) * the whole document *	1,2,4,7	A61N1/365 A61B8/06
Y	EP-A-0 347 708 (CARDIAC PACEMEKERS INC) * the whole document *	1,2,4,7	
A	EP-A-0 074 126 (PURDUE RESEARCH FOUNDATION) * the whole document *	1,2,4,7	
A,D	US-A-4 600 017 (E.A. SCHROEPPEL) * the whole document *	1,2,4,7	
A	US-A-4 733 667 (A.L. OLIVE ET AL.) * the whole document *	5,6,10	
A	BIOMEDIZINISCHE TECHNIK. vol. 34, no. 7/8, July 1989, BERLIN DE pages 177 - 184; M. SCHALDACH: 'PEP-gesteurter Herzschrittmacher' * the whole document *	8,9	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	23 APRIL 1992	FERRIGNO A.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P0401)